MAY 26–28

ISCT2021 NEW ORLEANS

VIRTUAL

Orchestrating Global CGT Translation
Building Consensus for the Path Forward

PROGRAM

International Society
ISCT
Cell & Gene Therapy®

WELCOME FROM THE ISCT PRESIDENT

Dear Friends and Colleagues,

We ARE friends AND colleagues! Just as ISCT is a Society like no other, ISCT 2021 Virtual New Orleans will continue our breakthrough last year in providing a virtual platform with industry leading presentation technology that is immersive and informative, enlightening and engaging in a multi-dimensional platform that reflects our Society values. We promote innovation in translational research. We strive for excellence in everything we do. We respect and support diversity and inclusivity. We uphold the highest ethical standards. We serve our members and advocate for our Society.

Over the past year, the world has seen great tragedy and scientific advances to meet pandemic challenges. The field of cell and gene therapy continues to break new ground, advancing medical care for patients worldwide. Recognizing that our field is at a crossroads, we've built the program around a theme**: "Orchestrating Global CGT Translation: Building Consensus for the Path Forward"**. That is why I am so grateful and proud of our Organizing Committee led by co-chairs Jaap Boelens, MD, PhD, (Chair, Stem Cell Engineering Committee), Karen Nichols, Esq. (ISCT Chief Regulatory Officer), and George Muschler, MD (Co-Chair, Orthopedic and Musculoskeletal Therapies Committee). Why is the ISCT 2021 New Orleans Virtual different from all other meetings? On a mission, and with incredible passion, the Organizing Committee has crafted an absolutely stellar program reflecting the translational pathway, integrating our Scientific Committees, our Commercialization Committee, our Global Regulatory Task Force, our Lab Practices Committee, and our Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapies. This integration reflects the orchestration of teams needed to develop cell and gene therapies, technologists, academics, manufacturing experts, clinicians, quality assurance teams, regulators, industry members, laboratory specialists, advanced practice practitioners, pharmacists, clinical research nurses and coordinators.

At ISCT 2021 New Orleans Virtual, from your home or office, or local park if you wish, you will explore a virtual environment made just for you and your interests. You will be able to network with peers, see leading exhibits, posters, and presentations and discussions with a constellation of global experts- the majority of which will be LIVE May 26-28 (9 hours a day, 3 concurrent tracks), and all of which will be available for viewing on demand for the remainder of 2021. Extra effort has been invested for enhanced virtual Networking, with a full ISCT 2021 Networking Day on May 25. During the Networking Day, you can attend the inaugural Investigators to Investors (I to I) Workshop, organized by the ISCT Business Models & Investment Commercialization Sub-Committee, which will bring together cell and gene therapy investors for a half-day educational event providing unparalleled access to cell and gene therapy key opinion leaders.

The anchor for your ISCT program is the six plenary sessions. Leading off, our President Elect Jacques Galipeau will chair the plenary "COVID-19: Understanding the Path Forward for Mesenchymal Stromal Cell Therapies." For the Presidential Plenary, representing the Commercialization Theme, "Integrating Science, Regulatory Oversight, and Commercialization for the New Wave of Cell and Gene Therapies" will feature a scientific leader (Matthew Porteus of Stanford), a regulatory leader (Peter Marks of FDA-CBER), and an industry leader (Arie Belldegrun of Allogene, formerly CEO of Kite). Each will take you through their personal career journey, the state of the field, and discuss paths forward. I am very excited that for the first time, the Presidential Plenary will have a co-chair, Early Stage Professional Shabnum Patel, PhD, as part of a new ISCT leadership mentoring program. One of the more rapidly developing areas of our field will be featured in Plenary III, "First in Man Exosome Trials". Plenary IV will feature a moderated (largely peaceful?) debate with leading experts on "BMT vs Gene Therapy vs No Cell Therapy: Accessibility, Cost, and Outcomes", Plenary V will chart the future for "Safe and Effective Translation in Tissue Engineering and Regenerative Medicine" and the finale, Plenary VI from the ISCT Immuno & Gene Therapies Committee will debate the applications of CAT-T/NK Cells: "Perspectives on Autologous versus Allogeneic Therapies." Supplementing these Plenaries will be Program Track sessions in six key topic areas in translational science, as well as key issues in regulation and industry: Mesenchymal Stromal Cells, Commercialization, Exosomes, Stem Cell Engineering, Tissue Engineering & Regenerative Medicine, and Immuno & Gene Therapies. Corporate Symposia, Tutorials, and Global Showcase sessions will feature the latest technology developments. But wait, there's more! Four Regulatory sessions, three Lab & Cell Processing sessions, a Veterinary Medicines

session, and two Advanced Practice Professionals sessions round out the programming May 26-28, remembering that all LIVE and pre-recorded sessions will be available through December 31, 2021. Also be sure not to miss the presentations of three ISCT awards for Career Achievement to Donald Kohn, MD., PhD, the inaugural Darwin J. Prockop Mentoring Award to ISCT Past President Cath Bollard, MBChB, MD, and the inaugural Le Prix Luc Sensebé Innovation Award, to Keith Thompson CBE, and much more.

Make sure you tune in for the launch of 'ISCT TV'! Join ISCT leaders as they live stream on YouTube before and after the Plenary Sessions for a community based approach to recreating the hallway conversations and coffee chats we miss in a virtual setting. Plus, see exclusive behind the scenes footage of our virtual meeting – there will be bloopers! It's engaging, it's fun, it's ISCT.

I would like to thank Jaap, Karen, George and the entire Organizing Committee and our extraordinary Head Office staff for exceptional effort in bringing this meeting to you. Enjoy, learn, connect, and let us all work towards a recovery where we can laissez les bons temps rouler!

Bruce Levine, *PhD*
ISCT President
June 2020 – June 2022

WELCOME FROM THE ISCT 2021 CO-CHAIRS

A warm welcome to ISCT 2021 New Orleans VIRTUAL!

This year's Annual Meeting is a testament to the unprecedented resilience shown by the cell and gene therapy community of ISCT. We welcome you to re-connect, communicate, and translate at ISCT 2021 New Orleans VIRTUAL, a LIVE and engaging meeting.

Our theme this year is, *Orchestrating Global CGT Translation: Building Consensus for the Path Forward,* and the key questions we and our field must undertake to solve as we approach a new wave of cell and gene therapies.

We have organized an Annual Meeting that includes the diverse perspectives of our membership in science, regulation, and commercialization, so that we can drive concerted and impactful advancement across the field and around the globe.

Our meeting spans six key themes, as well as sessions on regulatory perspectives and leading industry innovations:

- Mesenchymal Stromal Cells
- Exosomes
- Stem Cell Engineering
- Tissue Engineering & Regenerative Medicine
- Immuno & Gene Therapies
- Commercialization

Each theme is spearheaded by a plenary session covering major challenges and opportunities in the field. Each theme is then further developed in four related sessions utilizing key opinion leaders to shine a light on in-depth approaches and crucial developments from their fields of expertise. Each year, ISCT meetings bring together the very best in the cell and gene therapy field to debate hot topics and present state of the art research. This year, we are proud to bring you over 200 preeminent speakers and chairs, whose *raison d'être* will be to share with you the information and the insights that will shape the future of the field as we begin the new wave of cell and gene therapies.

In a year where we long to regain personal interactions beyond video calls and recordings, we have worked to create an engaging interactive experience with many features of an in-person meeting. Prepare yourselves for the hustle and bustle that are the trademark of any meeting worth attending!

Tune into live discussions of ongoing events in the community-driven programing unveiled in ISCT TV! ISCT TV will provide insider perspectives on past and upcoming sessions, and how key session insights connect across the meeting on the theme of building consensus. Led by our virtual hosting teams and ESP ambassadors, ISCT TV is above all, a perfect opportunity to see the ISCT community in action as you enjoy a cup of coffee, or even a glass of wine, before your next session begins!

It was important for us to incorporate the feedback you provided after ISCT 2020 – so, this year's meeting will provide improved networking and partnering opportunities. The ISCT 2021 Networking Day provides delegates with a full day of activities before LIVE sessions begin. Keep an eye out for sessions tailored to your interests:

- Regional Town Halls
- ESP Networking Sessions
- Investigators to Investors (I to I) Workshop
- Poster Hall

Chat or video call one-to-one with your colleagues around the globe as you participate in all the activities of the ISCT 2021 Networking Day.

Visit the exhibit hall to see exciting and state of the art innovations from industry partners and members. Keep an eye out for a great suite of Corporate Symposia, Tutorials, Global Showcase Presentations, and Hot Topic Roundtables.

Deepest thanks to all the members who have contributed to making this program a reality. Members from around the globe on the organizing committee, speaker roster, the ISCT committees, and many others have come together to create a community spirit and a virtual event like no other. Please enjoy four days of engaging presentations, focused networking, and excitement with our colleagues from around the globe. Our sincere best wishes to you and your families, friends, and teams. We look forward to seeing you at **ISCT 2021 New Orleans VIRTUAL.**

Jaap Jan Boelens, *MD, PhD*
ISCT 2021 Co-Chair
Memorial Sloan
Kettering Cancer Center
New York, United States

Karen Nichols, *Esq.*
ISCT 2021 Co-Chair
Vertex Therapeutics
Cambridge, United States

George Muschler, *MD*
ISCT 2021 Co-Chair
Cleveland Clinic
Cleveland, United States

PROGRAM AT A GLANCE

24/7 Access to ON-DEMAND Education, Poster Hall, and Exhibit Hall
Live support available from 07:00 EDT to 21:00 EDT on live meeting dates.

TUESDAY, MAY 25

North America PDT	North America **EDT**	Europe CEST	Asia JST	Australia AEDT	NETWORKING EVENTS AND POSTER SESSIONS	
04:00-05:00	**07:00-08:00**	13:00-14:00	20:00-21:00	21:00-22:00	Asia Regional Town Hall	
07:00	**10:00**	16:00	23:00	00:00	Virtual Environment Opens	Investigators to Investors (I to I) Networking Workshop
07:30-08:30	**10:30-11:30**	16:30-17:30	23:30-00:30	00:30-01:30	Early Stage Professionals (ESP) Networking Session 1	
08:30	**11:30**	17:30	00:30	01:30	Europe Regional Town Hall	
09:30-11:00	**12:30-14:00**	18:30-20:00	01:30-03:00	02:30-04:00	Poster Session 1	**Exhibit Hall Reception**
11:00-12:00	**14:00-15:00**	20:00-21:00	03:00-04:00	04:00-05:00	ISCT AGM *Annual General Meeting*	
14:00-15:00	**17:00-18:00**	23:00-0:00	06:00-07:00	07:00-08:00	South & Central America Regional Town Hall	
15:00-16:00	**18:00-19:00**	00:00-01:00	07:00-08:00	08:00-09:00	Early Stage Professionals (ESP) Networking Session 2	
16:00-17:00	**19:00-20:00**	01:00-02:00	08:00-09:00	09:00-10:00	Australia & New Zealand Regional Town Hall	
17:00-18:30	**20:00-21:30**	02:00-03:30	09:00-10:30	10:00-11:30	Poster Session 2	**Exhibit Hall Reception**

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM				ISCT TV
04:30	**07:30**	13:30	20:30	21:30					ISCT TV – With Hosts Rachele Ciccocioppo & Miguel Forte
05:00	**08:00**	14:00	21:00	22:00	**PLENARY 1 - COVID-19: UNDERSTANDING THE PATH FORWARD FOR MESENCHYMAL STROMAL CELL THERAPIES**				
06:30	**09:30**	15:30	22:30	23:30					ISCT TV – With Hosts Rachele Ciccocioppo & Miguel Forte
07:00	**10:00**	16:00	23:00	00:00	MSCs MSC-Derived EVs: Cell Therapy Without Cells	COMMERCIALIZATION Allogeneic Therapies – What Really is a Healthy Donor?	Translating Cellular Therapies from Bench to Clinic – The Critical Role of GMP-compliant, Scalable Cell Engineering Technology (MaxCyte Symposium)		
08:30	**11:30**	17:30	00:30	01:30	MSCs Debating MSC Tissue Sources: Biological and Manufacturing Considerations	COMMERCIALIZATION Naming Cell & Gene Therapies – Harmonizing with INN Nomenclature and Regulatory Impact – A Joint ISCT – WHO Session	REGULATORY The Path to a Biologics License Application (BLA)		
09:30	**12:30**	18:30	01:30	02:30				Successes and Failures Managing Clinical Trials in Apheresis Centers (Hot Topic Industry Roundtable) **Ends at 13:30 ET*	
10:00	**13:00**	19:00	02:00	03:00	**ISCT MAJOR AWARDS PRESENTATIONS** ***Followed by:*** **PRESIDENTIAL PLENARY – INTEGRATING SCIENCE, REGULATORY OVERSIGHT, AND COMMERCIALIZATION FOR THE NEW WAVE OF CELL AND GENE THERAPIES**				
12:00	**15:00**	21:00	04:00	05:00				Digital Transformation in Biologics Manufacturing & Quality Control Operations – L7 Informatics LIVE Expert Q&A Session	ISCT TV – With Hosts Daniel J. Weiss & Anthony Ting

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM				ISCT TV
12:30	**15:30**	21:30	04:30	05:30	MSCs Understanding Regulatory Requirements for Potency Assays	COMMERCIALIZATION The Economic Impact on Healthcare and the Future of Advanced Cell & Gene Therapy	Defining Intelligent Scale Up and Scale Out. How Small Decisions Have Major Implications for Intelligent Scale Up and Out (ScaleReady Symposium)		
14:00	**17:00**	23:00	06:00	07:00	MSCs Lessons & Recommendations for Clinical Trials of MSCs for Musculoskeletal Diseases in 2021	COMMERCIALIZATION Advancing the Translational Process through Automation & Equipment that Deliver Successful Scale Up/ Out in Cell Therapies	REGULATORY Phishing for Cell Therapies – Therapeutic Deception		
15:30	**18:30**	00:30	07:30	08:30					ISCT TV – With Hosts Daniel J. Weiss & Anthony Ting

THURSDAY, MAY 27

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM	ISCT TV
04:30	**07:30**	13:30	20:30	21:30		ISCT TV – With Hosts Rebecca Lim & Jaap Jan Boelens
05:00	**08:00**	14:00	21:00	22:00	**PLENARY 3 – "FIRST IN MAN" EXOSOME TRIALS**	
06:30	**09:30**	15:30	22:30	23:30		ISCT TV – With Hosts Rebecca Lim & Jaap Jan Boelens

THURSDAY, MAY 27

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM				ISCT TV
07:00	**10:00**	16:00	23:00	00:00	Exosomes Drug Delivery: The Therapeutic Power of Engineered EVs	Stem Cell Engineering Dilemmas in Transplantation for Acute Myeloid Leukemia	Kicking Off Cell Therapies With the Right Materials – Experts Weigh In (Cytiva Symposium)		
08:30	**11:30**	17:30	00:30	01:30	Exosomes Extracellular Vesicles as Future Therapeutics and Indicators of Cardiac Disease	Stem Cell Engineering Debating PTCy vs T-Cell Depletion for Treating Non-Malignant Diseases: Do we know which one is better?	Expanding the Possibilities of Cell Therapy (Miltenyi Biotec Symposium)		
09:30	**12:30**	18:30	01:30	02:30				Optimizing the Vein to Vein Pathway (Hot Topic Industry Roundtable) *Ends at 13:30 ET	
10:00	**13:00**	19:00	02:00	03:00			Pall Corporation LIVE Expert Q&A Session		ISCT TV – With Hosts Patrick Hanley & Lizette Caballero
10:30	**13:30**	19:30	02:30	03:30	**PLENARY 4 – BMT VS GENE THERAPY VS NO CELL THERAPY: ACCESSIBILITY, COST, AND OUTCOMES**				
12:00	**15:00**	21:00	04:00	05:00			How to Build A Logistics Platform For Autologous And Allogeneic Therapies – World Courier LIVE Expert Q&A Session		ISCT TV – With Hosts Patrick Hanley & Lizette Caballero
12:30	**15:30**	21:30	04:30	05:30	Traceability and Labeling for Cell-based Therapies and Regenerated Tissue	Stem Cell Engineering State of the Art in Cord Blood Transplantation: Banking, Expansion and Future Horizons – ISCT-WMDA Joint Session	Current and Future State of T Cell Therapy Manufacturing - Closing, Automating and Preparing for the T Cell Therapy Revolution (Thermo Fisher Scientific Symposium)		
14:00	**17:00**	23:00	06:00	07:00	Exosomes EVs for Infectious Diseases and Preparedness for Future Pandemics – ISCT-ISEV Joint Session	Stem Cell Engineering Tuning the Immune System to Optimize the Efficacy of Cellular Therapies	Cellicon Valley: Building a Thriving Cell & Gene Therapy Ecosystem Leveraging Academia and Industry (Penn Medicine Symposium) *Ends at 18:00 ET		
15:30	**18:30**	00:30	07:30	08:30					ISCT TV – With Hosts Patrick Hanley & Lizette Caballero

FRIDAY, MAY 28

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM				ISCT TV
04:30	**07:30**	13:30	20:30	21:30					ISCT TV – With Hosts George Muschler & Massimo Dominici
05:00	**08:00**	14:00	21:00	22:00	**PLENARY 5 - CHARTING THE FUTURE – SAFE AND EFFECTIVE TRANSLATION IN TISSUE ENGINEERING AND REGENERATIVE MEDICINE**				
06:30	**09:30**	15:30	22:30	23:30					ISCT TV – With Hosts George Muschler & Massimo Dominici
07:00	**10:00**	16:00	23:00	00:00	REGENERATIVE MEDICINE & TISSUE ENGINEERING New Horizons for Cell Therapies to Treat Cardiovascular Diseases	IMMUNO & GENE THERAPY Lymphodepletion and Biomarkers in Cell Therapy	The Development Trend and Clinical Application of Novel Automated CAR T-cell Expansion Technology (Terumo BCT Symposium) *Ends at 11:00 ET*		
08:30	**11:30**	17:30	00:30	01:30	REGENERATIVE MEDICINE & TISSUE ENGINEERING Networks and Dynamics in the Clinical Translation of Safe and Effective Cellular Therapies for Musculoskeletal Diseases	IMMUNO & GENE THERAPY Novel Allo-Engineering Approaches and Progress in Off-the-Shelf Products	Strategies for Implementing Rapid Mycoplasma Testing Methods to Advance QC in Cell and Gene Therapy Manufacturing (Roche CustomBiotech Symposium) *Ends at 12:15 ET*		
09:30	**12:30**	18:30	01:30	02:30				Preparing for the Future of CAR T Manufacturing (Hot Topic Industry Roundtable)	
10:00	**13:00**	19:00	02:00	03:00					ISCT TV – With Hosts George Muschler, Massimo Dominici, Karen Nichols & Daniel J. Weiss
10:30	**13:30**	19:30	02:30	03:30	**PLENARY 6 – DEBATING APPLICATIONS OF CAR-T/NK CELLS: PERSPECTIVES ON AUTOLOGOUS VERSUS ALLOGENEIC THERAPIES**				

FRIDAY, MAY 28

North America PDT	North America **EDT**	Europe CEST	Asia JST	Australia AEDT	LIVE AUDITORIUM				ISCT TV
12:00	**15:00**	21:00	04:00	05:00				Accelerating Clinical Readiness and Speed to Market of CAR T Therapies (Hot Topic Industry Roundtable) **Ends at 16:00 ET*	ISCT TV – With Hosts Karen Nichols & Daniel J. Weiss
12:30	**15:30**	21:30	04:30	05:30	REGENERATIVE MEDICINE & TISSUE ENGINEERING Regenerative Engineering for Nervous System Diseases	IMMUNO & GENE THERAPY Progress in In-Vivo Gene Therapies	REGULATORY Understanding the Necessary Conditions for First in Human Trials		
14:00	**17:00**	23:00	06:00	07:00	REGENERATIVE MEDICINE & TISSUE ENGINEERING Cell and Biomaterials based Technologies in GI Bioengineering: Approaching the Bedside	IMMUNO & GENE THERAPY Cell Therapy and the Spleen: Modulating Therapeutic Outcomes After Inflammatory Crises or Injury Onset	REGULATORY Global Regulatory Perspectives		
15:30	**18:30**	00:30	07:30	08:30					ISCT TV – With Hosts Karen Nichols & Daniel J. Weiss

LIVE PROGRAM

All LIVE education sessions and panel discussions will be recorded and available on-demand within 24 hours and until December 31, 2021

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
04:30-05:00	**07:30-08:00**	13:30-14:00	20:30-21:00	21:30-22:00	**ISCT TV – WITH HOSTS RACHELE CICCOCIOPPO *(IT)* & MIGUEL FORTE *(BE)*** • ISCT 2021 Welcome Address from President & Organizing Committee • Introduction to Early Stage Professional (ESP) Reporters • Plenary 1 Preview
05:00-06:30	**08:00-09:30**	**14:00-15:30**	**21:00-22:30**	**22:00-23:30**	**PLENARY 1 – COVID-19: UNDERSTANDING THE PATH FORWARD FOR MESENCHYMAL STROMAL CELL THERAPIES** ***Chair:*** **Jacques Galipeau** *(US)* ***Speakers:*** **Patricia Rocco** *(BR) – Rationale for Mesenchymal Stromal Cells to Treat COVID-19 Respiratory Failure* **Maroun Khoury** *(CL) – The Coronavirus Pandemic: A Pitfall or a Fast Track for Validating Cell Therapy Products?* **Anthony Ting** *(US) – Industry-Sponsored Cell Therapy Trials for COVID-19 Induced ARDS – An Update* ***Oral Abstract Presentations:*** **Rita Barcia** *(US) – Extracorporeal Mesenchymal Stromal Cell Therapy (SBI-101) in severe COVID-19 complicated by Acute Kidney Injury (Abstract 9)* **Tomer Bronshtein** *(IL) – MesenCure—an enhanced cell therapy explicitly developed for treating acute respiratory distress in Covid-19: From benchtop to bedside (Abstract 10)* **Duncan Stewart** *(CA) – Results of the Cellular Immuno-Therapy for COVID-19 related Acute Respiratory Distress Syndrome (CIRCA-19) Phase I Trial (Abstract 11)* **Silviu Itescu** *(AU) – Remestemcel-L for COVID-19 ARDS*
06:30-07:00	**09:30-10:00**	15:30-16:00	22:30-23:00	23:30-00:00	**ISCT TV – WITH HOSTS RACHELE CICCOCIOPPO *(IT)* & MIGUEL FORTE *(BE)*** • Fireside Chat: Plenary Debrief – What did we learn? • Preview ISCT awards and Presidential Plenary
07:00-08:30	**10:00-11:30**	16:00-17:30	23:00-00:30	00:00-01:30	**MSC SESSION 1 – MSC-DERIVED EVS: CELL THERAPY WITHOUT CELLS** ***Chair:*** **Donald Phinney** *(US)* ***Speakers:*** **Sai Kiang Lim** *(SG) – MSC-Derived EVs: Challenges and Opportunities in Cell Therapy Without Cells* **Bas van Balkom** *(NL) – Proteomic Signature of Mesenchymal Stromal Cell-derived Extracellular Vesicles* **Claudia dos Santos** *(CA) – Mesenchymal Stromal Cells in the Treatment of Sepsis* **COMMERCIALIZATION SESSION 1 – ALLOGENEIC THERAPIES – WHAT REALLY IS A HEALTHY DONOR?** ***Chair:*** **Dominic Clarke** *(US)* ***Speakers:*** **David Sourdive** *(FR) – What really is a Healthy Donor?* **James Trager** *(US) – Donor Selection for Off-the-Shelf Natural Killer Cell Therapies* **Christopher Bravery** *(UK)* **Deborah Hursh** *(US)* **TRANSLATING CELLULAR THERAPIES FROM BENCH TO CLINIC – THE CRITICAL ROLE OF GMP-COMPLIANT, SCALABLE CELL ENGINEERING TECHNOLOGY** ***Moderator:*** **James Brady** *(US)* ***Speakers:*** **Céline Mahieu** *(US)*, **Melissa Elliot** *(US)*, **Babak Moghimi** *(US)*, **Angelo A. Cardoso** *(US)* *Symposium Hosted by* MaxCyte®

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
					MSC SESSION 2 – DEBATING MSC TISSUE SOURCES: BIOLOGICAL AND MANUFACTURING CONSIDERATIONS *Chair:* **Karin Tarte** *(FR)* *Speakers:* **Melanie Generali** *(CH) – Battle of the Best: Systematic Comparison of Secretome and Gene Signature* **Frank Barry** *(IE) – MSC Therapy for Osteoarthritis - Cell Source and Mechanism* **Ivan Martin** *(CH) – Tissue Specificity of MSCs for Regenerative Medicine* *Oral Abstract Presentations:* **Kristina Thamm** *(DE) – Modular Biomimetic Matrices Enable Highly Defined Culture of Functional Stem Cells (Abstract 12)* **Martha Arango-Rodriguez** *(CO) – Security and efficacy of intradermal injection of mesenchymal stem cells derivatives on chronic diabetic foot ulcers: a randomized controlled clinical trial (Abstract 13)*
08:30-10:00	**11:30-13:00**	17:30-19:00	00:30-02:00	01:30-03:00	**COMMERCIALIZATION SESSION 2 – NAMING CELL & GENE THERAPIES – HARMONIZING WITH INN NOMENCLATURE AND REGULATORY IMPACT – A JOINT ISCT – WHO SESSION** *Co-Chairs:* **Raffaella Balocco** *(CH)* & **Massimo Dominici** *(IT)* *Speakers:* **Raffaella Balocco** *(CH) – WHO INN: Naming Advanced Therapies* **Ursula Loizides** *(CH) – WHO INN Nomenclature Schemes for Cell and Gene Therapy Substances* **Harmonizing Cell & Gene Therapies:** **Tony Manderson** *(AU) – Challenges with INN Descriptions, and the Australian Perspective* **Marcos Timón** *(ES) – The EU Perspective* **Peter Marks** *(US) – The FDA Perspective* **Anthony Ting** *(US) – The Industry Perspective* **Kawaldip Sehmi** *(UK) – Patient Engagement and Co-Creation in Naming Cell & Gene Therapies – Harmonizing with INN Nomenclature and Regulatory Impact*
					REGULATORY SESSION 1 – THE PATH TO A BIOLOGICS LICENSE APPLICATION (BLA) *Co-Chairs:* **Victoria Dohnal** *(US)* & **Karen Nichols** *(US)* *Speakers:* **Luis Barrera** *(US) – Off-Target Testing in Gene-Edited Products* **Katie Miller** *(US) – Analytical Development for Cell/ Gene Therapies* *Panelists:* **Michael Mendicino** *(US)* **Mohammad Heidaran** *(US)*
09:30-10:30	**12:30-13:30**	18:30-19:30	01:30-02:30	02:30-03:30	**HOT TOPIC INDUSTRY ROUNDTABLE 1 – SUCCESSES AND FAILURES MANAGING CLINICAL TRIALS IN APHERESIS CENTERS** *Moderator:* **Joseph Schwartz** *(US)* *Panelists:* **Elizabeth Valdez** *(US)*, **Amy Duross** *(US)*, **Peter Holman** *(US)* *Sponsored By:* TERUMO BLOOD AND CELL TECHNOLOGIES, Vineti
10:00-12:00	**13:00-15:00**	19:00-21:00	02:00-04:00	03:00-05:00	**ISCT AWARDS PRESENTATIONS** **2021 Career Achievement Award** *presented to* **Donald B. Kohn** *(US)* **Darwin J. Prockop Mentoring Award** *presented to* **Catherine Bollard** *(US)* **Le Prix Luc Sensebé Innovation Award** *presented to* **Keith Thompson** *(UK)* *Followed by:* **PRESIDENTIAL PLENARY – INTEGRATING SCIENCE, REGULATORY OVERSIGHT, AND COMMERCIALIZATION FOR THE NEW WAVE OF CELL AND GENE THERAPIES** *Co-Chairs:* **Bruce Levine** *(US)* & **Shabnum Patel** *(US)* *Speakers:* **Peter Marks** *(US)* **Arie Belldegrun** *(US)* **Matthew Porteus** *(US)*
12:00-12:30	**15:00-15:30**	21:00-21:30	04:00-04:30	05:00-05:30	**ISCT TV – WITH HOSTS DANIEL J. WEISS** *(US)*, **KAREN NICHOLS** *(US)* **& ANTHONY TING** *(US)* • Fireside Chat – ISCT Chief Scientific, Regulatory & Commercial Officers: Presidential Plenary Debrief *Segment Sponsor:* ISCT TV, ScaleReady

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
12:00-12:30	**15:00-15:30**	21:00-21:30	04:00-04:30	05:00-05:30	**DIGITAL TRANSFORMATION IN BIOLOGICS MANUFACTURING & QUALITY CONTROL OPERATIONS** **LIVE Expert Q&A Session Hosted by L7 Informatics** *Experts:* **John Conway** *(US)*, **Trent Carrier** *(US)*, **Brennen Wright** *(US)*, **Steven Barash** *(US)*
12:30-14:00	**15:30-17:00**	21:30-23:00	04:30-06:00	05:30-07:00	**MSC SESSION 3 – UNDERSTANDING REGULATORY REQUIREMENTS FOR POTENCY ASSAYS** *Chair:* **Sowmya Viswanathan** *(CA)* *Speakers:* **Mauro Krampera** *(IT) – Overview of Cell-Based Assays for Translational Use (Guidelines, Common Assays, Gaps, Etc.)* **Steven Bauer** *(US) – FDA Perspectives on Potency for Cell Therapies* **Eleuterio Lombardo** *(ES) – Thoughts on MSC Therapy Potency Assays* *Oral Abstract Presentations:* **Pallab Pradhan** *(US) – Multiomic Analysis and Computational Modeling to Identify Critical Quality Attributes for Immunomodulatory Potency of Mesenchymal Stromal Cells (Abstract 14)* **Razieh Rabani** *(US) – MicroRNA Signature of Mesenchymal Stromal Cells Contributes to their Therapeutic Efficacy in the Context of Osteoarthritis (Abstract 15)*
					COMMERCIALIZATION SESSION 3 – THE ECONOMIC IMPACT ON HEALTHCARE AND THE FUTURE OF ADVANCED CELL & GENE THERAPY *Co-Chairs:* **Julie Allickson** *(US)* & **Patrick Rivers** *(US)* *Speakers:* **Reni Benjamin** *(US) – Capital Markets and the Regenerative Medicine Space* **Matthew Durdy** *(US) – Realising the Full Economic and Societal Potential of Cell and Gene Therapy* **Stephanie Farnia** *(US) – U.S. Commercial Payer Perspectives*
					DEFINING INTELLIGENT SCALE UP AND SCALE OUT. HOW SMALL DECISIONS HAVE MAJOR IMPLICATIONS FOR INTELLIGENT SCALE UP AND OUT *Symposium Hosted by* *Chair:* **Juan Vera** *(US)* *Panelists:* **James Bolling** *(US)*, **J. Kelly Ganjei** *(US)*, **Tim Moore** *(US)*, **Michael Paglia** *(US)*, **Amos Tsai** *(US)*
14:00-15:30	**17:00-18:30**	23:00-00:30	06:00-07:30	07:00-08:30	**MSC SESSION 4 – LESSONS & RECOMMENDATIONS FOR CLINICAL TRIALS OF MSCS FOR MUSCULOSKELETAL DISEASES IN 2021** *Co-Chairs:* **Christian Jorgensen** *(FR)* & **George Muschler** *(US)* *Speakers:* **Felipe Prosper** *(ES) – Application of Mesenchymal Stromal Cells from Treatment of Osteoarticular Diseases* **Norimasa Nakamura** *(JP) – Adipose Derived Stem Cell versus Stromal Vascular Fraction Injection for Treatment of Knee Osteoarthritis* **Oscar Lee** *(TW) – Cell Therapy for OA knee: An Update*
					COMMERCIALIZATION SESSION 4 – ADVANCING THE TRANSLATIONAL PROCESS THROUGH AUTOMATION & EQUIPMENT THAT DELIVER SUCCESSFUL SCALE UP/ OUT IN CELL THERAPIES *Chair:* **John McMannis** *(US)* *Speakers:* **Megan (Suhoski) Davis** *(US)* **Martin Giedlin** *(US) – Perspective on their Approach to Automation* **Jason Foster** *(UK) – Ori Biotech: Manufacturing Brighter Futures* **Fabian Gerlinghaus** *(US) – Cellares - An Introduction to the Cell Shuttle*
					REGULATORY SESSION 2 – PHISHING FOR CELL THERAPIES – THERAPEUTIC DECEPTION *Session Sponsor:* *Co-Chairs:* **Laertis Ikonomou** *(US)* & **Patti Zettler** *(US)* *Speakers:* **Virginia Lyons** *(US) – Policy: Stem Cell Clinics and Patient Safety* **Elizabeth Nach** *(US) – FTC Advertising Law and Stem Cell Therapy Claims* **Eric McIntosh** *(AU) – Advertising of Biologicals to the Public in Australia*

WEDNESDAY, MAY 26

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
15:30-15:45	**18:30-18:45**	00:30-00:45	07:30-07:45	08:30-08:45	**ISCT TV – WITH HOSTS DANIEL J. WEISS** *(US)* **& ANTHONY TING** *(US)* *Segment Sponsor:* ScaleReady.

THURSDAY, MAY 27

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
04:30-05:00	**07:30-08:00**	**13:30-14:00**	**20:30-21:00**	**21:30-22:00**	**ISCT TV – WITH HOSTS REBECCA LIM** *(AU)* **& JAAP JAN BOELENS** *(US)*
05:00-06:30	**08:00-09:30**	14:00-15:30	21:00-22:30	22:00-23:30	**PLENARY 3 – "FIRST IN MAN" EXOSOME TRIALS** ***Co-Chairs:*** **Sai Kiang Lim** *(SG)* ***&*** **Maurizio Muraca** *(IT)* ***Speakers:*** **Eva Rohde** *(AT) – Naïve Stromal Cell Derived Extracellular Vesicles – Animal Models and First-in-Human Experience* **Andrew Hoffman** *(US) – Clinical Trials in Veterinary Patients Can Inform and Accelerate Translation of Cell and Exosome Based Therapies* **Massimo Dominici** *(IT) – From Cells to Vesicles: Challenges and Opportunities Towards a Therapeutic Nanoscale Transition*
06:30-07:00	**09:30-10:00**	15:30-16:00	22:30-23:00	23:30-00:00	**ISCT TV – WITH HOSTS REBECCA LIM** *(AU)* **& JAAP JAN BOELENS** *(US)*
07:00-08:30	**10:00-11:30**	16:00-17:30	23:00-00:30	00:00-01:30	**EXOSOMES SESSION 1 – DRUG DELIVERY: THE THERAPEUTIC POWER OF ENGINEERED EVS** ***Chair:*** **Bernd Giebel** *(DE)* ***Speakers:*** **Samir El Andaloussi** *(SE) – Bioengineering of Extracellular Vesicles for Delivery of Biotherapeutics* **Chulhee Choi** *(KR) – Novel Exosome-Based Intracellular Delivery of Protein Therapeutics* **Minh Le** *(SG) – Efficient and Safe Delivery of Therapeutic RNAs Using Extracellular Vesicles from Red Blood Cells* ***Oral Abstract Presentations:*** **David García-Bernal** *(ES) – Human bone marrow mesenchymal stromal cell-derived extracellular vesicles modified by enzymatic exofucosylation prevent acute graft-versus-host disease progression (Abstract 16)* **Jiajun Shi** *(SG) – MSC exosomes enhance dental pulp cell functions through CD73/ecto-5'-nucleotidase activity (Abstract 17)*
					STEM CELL ENGINEERING SESSION 1 – DILEMMAS IN TRANSPLANTATION FOR ACUTE MYELOID LEUKEMIA ***Co-Chairs:*** **Duncan Purtill** *(AU)* ***&*** **Robert Wynn** *(UK)* ***Speakers and Debate Panel:*** **David Curtis** *(AU) – Measurable Residual Disease for Guiding our Transplant Decisions* **Juliet Barker** *(US) – Treating High Risk AML: Current Dilemmas in Clinical Practice* **Ivana Gojo** *(US)* **Kanya Rajangam** *(US) – CAR NK and CAR T Therapies for AML* **Charles Craddock** *(UK) – Maintenance and other Drug Therapies for AML after Allogeneic Transplantation*
					KICKING OFF CELL THERAPIES WITH THE RIGHT MATERIALS – EXPERTS WEIGH IN *Symposium Hosted by* cytiva ***Chair:*** **Gary M. Pigeau** *(CA)* ***Speakers:*** **Lauren Ritchie** *(US)*, **Jason Dowd** *(CA)*, **Marc Turner** *(SC)*

THURSDAY, MAY 27

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
					EXOSOMES SESSION 2 – EXTRACELLULAR VESICLES AS FUTURE THERAPEUTICS AND INDICATORS OF CARDIAC DISEASE *Co-Chairs:* **Dominique de Kleijn** *(NL)* & **Andrew Hoffman** *(US)* *Speakers:* **Eduardo Marban** *(US) – Deconstructing Regenerative Medicine: From Cells to EVs and Defined Factors* **Vicky Yang** *(US) – Extracellular Vesicle Associated Non-Coding RNA in Cardio-Oncology and Mitral Valve Disease in the Canine Model* **Saumya Das** *(US) – The Role of Extracellular Vesicles and their Cargos in Cardiac Remodeling* *Oral Abstract Presentations:* **Federica Marinaro** *(ES) – Infiltrated platelets in infarcted myocardium as a target for extracellular vesicles from endometrial-derived mesenchymal stromal cells after intrapericardial administration. (Abstract 18)* **Marta Monguió-Tortajada** *(ES) – Extracellular vesicles from mesenchymal stromal cells combined with tissue engineering improve cardiac function, reduce fibrosis and modulate immune response in acute myocardial infarcted pigs (Abstract 19)*
08:30-10:00	**11:30-13:00**	17:30-19:00	00:30-02:00	01:30-03:00	**STEM CELL ENGINEERING SESSION 2 – DEBATING PTCY VS T-CELL DEPLETION FOR TREATING NON-MALIGNANT DISEASES: DO WE KNOW WHICH ONE IS BETTER?** *Co-Chairs:* **Carmem Bonfim** *(BR)* & **Alice Bertaina** *(US)* *Speakers and Debate Panel:* **Carmem Bonfim** *(BR) – Debating the Best Stem Cell Sources for Treating Fanconi Anemia* **Parinda Mehta** *(US) – HCT for Fanconi Anemia: To T-Cell Deplete the Graft or Not?* **Joseph Oved** *(US) – The Role of TCRa/b T-Cell Depleted HSCT in Patients with Severe Acquired Aplastic Anemia* **Amy DeZern** *(US) – SAA, Alternative Donors, and PTCy* **Orly Klein** *(US) – Debating the Best Stem Cell Sources for Treating Non-Malignant Diseases: Post-Transplant Cyclophosphamide* **Kanchan Rao** *(UK) – T Cell Depletion in PID*
					EXPANDING THE POSSIBILITIES OF CELL THERAPY *Chair:* **Caroline Blumer-Toti** *(US)* *Speakers:* **Boris Fehse** *(DE) – Clinical Scale CCR5 Knockout in Primary T Cells in the Clinimacs Prodigy* **Sandy Pelletier** *(FR) – Harnessing the Power of Tumor-Infiltrating Lymphocytes* **Moonsoo M. Jin** *(US) – Affinity-Tuned CAR T to Treat Tumors with Overexpressed Antigens: Phase I Study Against Advanced Thyroid Cancer* *Symposium Hosted by* Miltenyi Biotec
09:30-10:30	**12:30-13:30**	18:30-19:30	01:30-02:30	02:30-03:30	**HOT TOPIC INDUSTRY ROUNDTABLE 2 – OPTIMIZING THE VEIN TO VEIN PATHWAY** *Moderator:* **Mark Lowdell** *(UK)* *Panelists:* **Joseph Garrity** *(US)*, **Chris McClain** *(US)*, **Mark Sawicki** *(US)*, **Bill Shingleton** *(UK)* *Sponsored By:* BE THE MATCH BioTherapies · cytiva · cryoport systems · Lonza
					ISCT TV – WITH HOSTS PATRICK HANLEY *(US)* **& LIZETTE CABALLERO** *(US)* ISCT TV
10:00-10:30	13:00-13:30	19:00-19:30	02:00-02:30	03:00-03:30	**LIVE EXPERT Q&A SESSION HOSTED BY PALL CORPORATION** *Experts:* **Emmanuelle Cameau,** *Senior R&D Manager, Bioprocessing Research and Development, Pall Corporation, FRA* **Saadia Zakai,** *Product Development Manager, Gene Therapy, Pall Corporation, USA* PALL

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North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
10:30-12:00	**13:30-15:00**	19:30-21:00	02:30-04:00	03:30-05:00	**PLENARY 4 – BMT VS GENE THERAPY VS NO CELL THERAPY: ACCESSIBILITY, COST, AND OUTCOMES** *Co-Chairs:* **Jaap Jan Boelens** *(US)* & **Sandeep Soni** *(US)* *Speakers and Debate Panel:* **Suradej Hongeng** *(TH) – How I do Allogeneic SCT for all Thalassemias* **Alexis Thompson** *(US)* **Selim Corbacioglu** *(DE) – Haploidentical aß T-Cell Depleted Donor Transplantation Versus Gene Editing: Pro's and Con's* **Matthew Porteus** *(US)* **Deepa Manwani** *(US) – Accessibility, Costs and Outcome of Treatment for Hemoglobinopathies – Sickle Cell Disease*
12:00-12:30	**15:00-15:30**	21:00-21:30	04:00-04:30	05:00-05:30	**ISCT TV – WITH HOSTS PATRICK HANLEY** *(US)* **& LIZETTE CABALLERO** *(US)* **HOW TO BUILD A LOGISTICS PLATFORM FOR AUTOLOGOUS AND ALLOGENEIC THERAPIES** **LIVE Expert Q&A Session Hosted by World Courier** *Expert:* **Andrea Zobel,** Senior Director, Personalized Supply Chain, USA
12:30-14:00	**15:30-17:00**	21:30-23:00	04:30-06:00	05:30-07:00	**TRACEABILITY AND LABELING FOR CELL-BASED THERAPIES AND REGENERATED TISSUE** *Co-Chairs:* **Lizette Caballero** *(US)* & **Paul Ashford** *(UK)* *Speakers:* **Paul Ashford** *(UK) – Traceability* **Martin Hildebrandt** *(DE) – A Standardized Approach to RM Products: The Code Defines the Product* **Dawn Henke** *(US)* *Panelist:* **Julie Allickson** *(US)* **STEM CELL ENGINEERING SESSION 3 – STATE OF THE ART IN CORD BLOOD TRANSPLANTATION: BANKING, EXPANSION AND FUTURE HORIZONS – ISCT-WMDA JOINT SESSION** *Co-Chairs:* **Annalisa Ruggeri** *(IT)* & **Allistair Abraham** *(US)* *Speakers:* **Andromachi Scaradavou** *(US) – The Future of Cord Blood: More Banking or Use of Already Collected Cords* **Sergio Querol** *(ES) – The Future of Cord Blood: More Banking or Use of Already Collected Cords* **Catherine Bollard** *(US) – Cord Blood Derived VSTs as a Potential Off-The-Shelf Therapy* **May Daher** *(US) – CAR-NK Cells: The Next Wave of Cellular Therapy for Cancer* **Sandra Cohen** *(CA) – Cord Blood Expansion* **Mitchell Horwitz** *(US) – Omidubicel: A New Standard of Care for Umbilical Cord Blood Transplantation?* *Joint Session with:* WMDA **CURRENT AND FUTURE STATE OF T CELL THERAPY MANUFACTURING – CLOSING, AUTOMATING AND PREPARING FOR THE T CELL THERAPY REVOLUTION** *Chair:* **Xavier De Mollerat Du Jeu** *(US)* *Speakers:* **Sean Chang** *(US)*, **Evan Zynda** *(US)*, **David Shaw** *(US)*, **Ben Schilling** *(US)* *Symposium Hosted by* ThermoFisher SCIENTIFIC

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North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
14:00-15:30	**17:00-18:30**	23:00-00:30	06:00-07:30	07:00-08:30	**EXOSOMES SESSION 3 – EVS FOR INFECTIOUS DISEASES AND PREPAREDNESS FOR FUTURE PANDEMICS – ISCT-ISEV JOINT SESSION** ***Co-Chairs:*** **Daniel Weiss** *(US)* ***&*** **Sai Kiang Lim** *(SG)* ***Speakers:*** **Kenneth Witwer** *(US) – Extracellular Vesicles in the Response to Infectious Diseases* **Yong Song Gho** *(KR) – Overview of Bacterial Extracellular Vesicles: From Bench to Clinic* **Lorena Martin-Jaular** *(FR) – Extracellular Vesicles Containing ACE2 Efficiently Prevent Infection by SARS-CoV-2 Spike Protein-Containing Virus* ***Oral Abstract Presentation:*** **Michael Bellio** *(US) – Administration of Amniotic Fluid derived Extracellular Vesicle is Associated with Decreased CRP in COVID-19 Patients (Abstract 20)* *Joint Session with:* INTERNATIONAL SOCIETY for EXTRACELLULAR VESICLES
14:00-15:30	**17:00-18:30**	23:00-00:30	06:00-07:30	07:00-08:30	**STEM CELL ENGINEERING SESSION 4 – TUNING THE IMMUNE SYSTEM TO OPTIMIZE THE EFFICACY OF CELLULAR THERAPIES** ***Chair & Speaker:*** **Susan Prockop** *(US) – Simple Milestones of Immune Reconstitution are Modifiable by Conditioning and Predict Outcomes of Transplant* ***Speakers and Debate Panel:*** **Kenneth Weinberg** *(US) – Designing Grafts to Improve HSC Transplant Outcomes and Immune Reconstitution* **Marcel van den Brink** *(US) – The Role of Thymic Reconstitution in Effective Post-Transplant Immunity* **Jürgen Kuball** *(NL) – gdTCR and their Receptors for the Next Generation of CART* **Tamara Laskowski** *(US) – Engineering NK Cells to Persist in the Challenging Tumor Microenvironment*
					CELLICON VALLEY: BUILDING A THRIVING CELL AND GENE THERAPY ECOSYSTEM LEVERAGING ACADEMIA AND INDUSTRY IN GREATER PHILADELPHIA **Corporate Symposium Hosted by Penn Medicine** ***Session Chair:*** **John. S. Swartley** *(US)* ***Speakers:*** **Usman (Oz) Azam** *(US)* **Steven Kelly** *(US)* **Steven Nichtberger** *(US)* *Symposium Hosted by* Penn Medicine, Cabaletta Bio, carisma THERAPEUTICS, TMUNITY
15:30-15:45	**18:30-18:45**	00:30-00:45	07:30-07:45	08:30-08:45	**ISCT TV – WITH HOSTS PATRICK HANLEY** *(US)* **& LIZETTE CABALLERO** *(US)*

FRIDAY, MAY 28

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
04:30-05:00	**07:30-08:00**	13:30-14:00	20:30-21:00	21:30-22:00	**ISCT TV – WITH HOSTS GEORGE MUSCHLER** *(US)* **& MASSIMO DOMINICI** *(IT)*
05:00-06:30	**08:00-09:30**	14:00-15:30	21:00-22:30	22:00-23:30	**PLENARY 5 – CHARTING THE FUTURE – SAFE AND EFFECTIVE TRANSLATION IN TISSUE ENGINEERING AND REGENERATIVE MEDICINE** ***Co-Chairs:*** **Giuseppe Orlando** *(US)* ***&*** **Ranieri Cancedda** *(IT)* ***Speakers:*** **Graziella Pellegrini** *(IT) – Regenerative Medicine by Epithelia: Increasing the Complexity* **Anthony Atala** *(US) – Regenerative Medicine: Current Concepts and Changing Trends* **Rocky Tuan** *(HK) – Stem Cell-Based Musculoskeletal Tissue Engineering: To Repair, Restore, and Re-Create*
06:30-07:00	**09:30-10:00**	15:30-16:00	22:30-23:00	23:30-00:00	**ISCT TV – WITH HOSTS GEORGE MUSCHLER** *(US)* **& MASSIMO DOMINICI** *(IT)*

FRIDAY, MAY 28

North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
07:00-08:30	**10:00-11:30**	16:00-17:30	23:00-00:30	00:00-01:30	**TISSUE ENGINEERING & REGENERATIVE MEDICINE SESSION 1 – NEW HORIZONS FOR CELL THERAPIES TO TREAT CARDIOVASCULAR DISEASES** *Chair:* **Massimiliano Gnecchi** *(IT)* *Speakers:* **Jozef Bartunek** *(BE) – Cardiopoietic Stem Cell Therapy in Ischaemic Heart Failure* **Stefan Janssens** *(NL) – Mononuclear Cell Therapy for Myocardial Infarction: Latest Evidence from the BAMI Trial* **Giulio Pompilio** *(IT) – G-CSF for large STEMI*
					IMMUNOTHERAPY & GENE THERAPY SESSION 1 – LYMPHODEPLETION AND BIOMARKERS IN CELL THERAPY *Co-Chairs*: **Jaap Jan Boelens** *(US)* & **Michael Scordo** *(US)* *Speakers:* **Michael Scordo** *(US) – Estimating the Depth of Lymphodepletion: Real-World Fludarabine PK-PD Analyses in Adult & Pediatric Patients Receiving CAR-T Cell Therapy* **Cameron Turtle** *(US) – Effects of Lymphodepletion on CD19 CAR-T Cell Therapy for B Cell Malignancies* **David Teachey** *(US) – Biomarkers for Toxicity after Chimeric Antigen Receptor T-Cell Therapy* *Oral Abstract Presentations:* **Vanessa Fabrizio** *(US) – Fludarabine-Exposure Predicts Disease Control Following CD19-specific CAR T cell (tisagenlecleucel); A Report from Pediatric Real-World CAR Consortium (Abstract 21)*
					THE DEVELOPMENT TREND AND CLINICAL APPLICATION OF NOVEL AUTOMATED CAR T-CELL EXPANSION TECHNOLOGY *Chair:* **Augustus Kilgore** *(US)* *Speaker:* **Lei Yu** *(CN)* *Symposium Hosted by* TERUMO BLOOD AND CELL TECHNOLOGIES
08:30-10:00	**11:30-13:00**	17:30-19:00	00:30-02:00	01:30-03:00	**TISSUE ENGINEERING & REGENERATIVE MEDICINE SESSION 2 – NETWORKS AND DYNAMICS IN THE CLINICAL TRANSLATION OF SAFE AND EFFECTIVE CELLULAR THERAPIES FOR MUSCULOSKELETAL DISEASES** *Chair:* **George Muschler** *(US)* *Speakers:* **William Maloney** *(US) – AAOS- Registry Efforts and the Focus on Biologics* **Farshid Guilak** *(US) – Engineering Stem Cells with Synthetic Gene Circuits as Novel Therapeutic Delivery Systems* **Nicolas Piuzzi** *(US) – Advancing Cellular Therapies - Clinical Needs and Applications (Beyond "Unproven")* *Oral Abstract Presentations:* **Judith Krieger** *(DE) – »JOINTPROMISE«: Concept of a Multi-Step, Automated Platform for Precision Manufacturing of Joint Implants (Abstract 24)* **Jesil Kasamkattil** *(CH) – Spheroids Derived from Human Nasal Chondrocytes for Nucleus Pulposus Repair (Abstract 25)*
					IMMUNOTHERAPY & GENE THERAPY SESSION 2 – NOVEL ALLO-ENGINEERING APPROACHES AND PROGRESS IN OFF-THE-SHELF PRODUCTS *Co-Chairs:* **Patrick Hanley** *(US)* & **Margaret Lamb** *(US)* *Speakers:* **Maksim Mamonkin** *(US) – Off-the-Shelf CAR T-Cells Resistant to Host Immune Rejection* **Jason Dubovsky** *(US) – Strategic Advantages Using Viral Specific T-cells as a Platform for Allogeneic CAR-T Therapy* **Lawrence Lamb** *(US) – Allogeneic Off-the-Shelf gdT Cell Engineering for Treatment Glioblastoma* *Oral Abstract Presentations:* **Michelle Cox** *(US) – GM-CSF Disruption in CART Cells Ameliorates CART Cell Activation and Reduces Activation-Induced Cell Death (Abstract 23)* **Cristina Ferreras** *(ES) – A Phase I/II Dose-Escalation Single Center Study to Evaluate the Safety of Infusion of Memory T Cells as Adoptive Therapy in Coronavirus Pneumonia and/ or Lymphopenia (Release) (Abstract 22)*

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North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
08:30-10:00	**11:30-13:00**	17:30-19:00	00:30-02:00	01:30-03:00	**STRATEGIES FOR IMPLEMENTING RAPID MYCOPLASMA TESTING METHODS TO ADVANCE QC IN CELL AND GENE THERAPY MANUFACTURING** **CORPORATE SYMPOSIUM HOSTED BY ROCHE CUSTOMBIOTECH** *Symposium Hosted by* Roche ***Chair:*** **Evonne R. Fearnot** *(US)* ***Speakers:*** **Sarah Snykers** *(BE)* **Sowmya Viswanathan** *(CA)*
09:30-10:30	**12:30-13:30**	18:30-19:30	01:30-02:30	02:30-03:30	**ISCT TV – WITH HOSTS GEORGE MUSCHLER** *(US)*, **MASSIMO DOMINICI** *(IT)*, **KAREN NICHOLS** *(US)* **& DANIEL J. WEISS** *(US)* *Segment Sponsor* MaxCyte **HOT TOPIC INDUSTRY ROUNDTABLE 3 – PREPARING FOR THE FUTURE OF CAR T MANUFACTURING** *Sponsored By:* AVECTAS, BERKELEY LIGHTS, RESILIENCE ***Moderator:*** **Bruce Levine** *(US)* ***Panelists:*** **David DiGiusto** *(US)*, **James Lovgren** *(US)*, **Michael Maguire** *(IE)*
10:30-12:00	**13:30-15:00**	19:30-21:00	02:30-04:00	03:30-05:00	**PLENARY 6 – DEBATING APPLICATIONS OF CAR-T/NK CELLS: PERSPECTIVES ON AUTOLOGOUS VERSUS ALLOGENEIC THERAPIES** ***Chair:*** **Michael Gustafson** *(US)* ***Speakers and Debate Panel:*** **Rayne Rouce** *(US)* **Richard Anderson** *(US)*
12:00-13:00	**15:00-16:00**	21:00-22:00	04:00-05:00	05:00-06:00	**ISCT TV – WITH HOSTS KAREN NICHOLS** *(US)* **& DANIEL J. WEISS** *(US)* *Segment Sponsor* MaxCyte
12:00-13:00	**15:00-16:00**	21:00-22:00	04:00-05:00	05:00-06:00	**HOT TOPIC INDUSTRY ROUNDTABLE 4 – ACCELERATING CLINICAL READINESS AND SPEED TO MARKET OF CAR T THERAPIES** *Sponsored By:* Miltenyi Biotec, G-CON MANUFACTURING INC., LYKAN BIOSCIENCE ***Moderator:*** **Patrick Hanley** *(US)* ***Panelists:*** **Ken LeClair** *(US)*, **Peter Makowenskyj** *(US)*, **Kunal Patel** *(US)*
12:30-14:00	**15:30-17:00**	21:30-23:00	04:30-06:00	05:30-07:00	**TISSUE ENGINEERING & REGENERATIVE MEDICINE SESSION 3 – REGENERATIVE ENGINEERING FOR NERVOUS SYSTEM DISEASES** ***Chair & Speaker:*** **Budd Tucker** *(US)* – *Treating Heritable Blindness* ***Speakers:*** **Clive Svendsen** *(US)* **Molly Shoichet** *(CA)* – *Regenerating the Brain after Stroke*
					IMMUNOTHERAPY & GENE THERAPY SESSION 3 – PROGRESS IN IN-VIVO GENE THERAPIES ***Co-Chairs:*** **Sandeep Soni** *(US)* ***&*** **Nicole Paulk** *(US)* ***Speakers:*** **Nicole Paulk** *(US)* – *Overview of AAV for Gene Therapies* **Krystof Bankiewicz** *(US)* – *MR-Guided Gene Delivery to the Brain* **Lindsey George** *(US)* – *Hemophilia Gene Therapy: What's Next?*
					REGULATORY SESSION 3 – UNDERSTANDING THE NECESSARY CONDITIONS FOR FIRST IN HUMAN TRIALS ***Co-Chairs:*** **Karen Nichols** *(US)* ***&*** **Karen Major** *(CA)* ***Speakers:*** **Aisha Khan** *(US)* – *Master Cell Banking and Testing - ESCs, iPSCs (Cells Banked for Further Differentiation)* **Patrick Au** *(US)* – *Selection of Animal Species/Models for Preclinical Testing of Cell and Gene Therapy Products* **Fouad Atouf** *(US)* – *Management of Raw Materials for the Manufacturing of Cell and Gene Therapies*

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North America PDT	North America EDT	Europe CEST	Asia JST	Australia AEDT	
					TISSUE ENGINEERING & REGENERATIVE MEDICINE SESSION 4 – CELL AND BIOMATERIALS BASED TECHNOLOGIES IN GI BIOENGINEERING: APPROACHING THE BEDSIDE *Co-Chairs:* **Rachele Ciccocioppo** *(IT)* & **Vincenzo Cardinale** *(IT)* *Speakers:* **Paolo De Coppi** *(UK) – Engineering Intestine for Therapy: A Step Approach* **Ekaterine Berishvili** *(CH) – Generation of Endocrine Pancreas Using Placental Derivatives* **Geraldine Mitchell** *(AU) – Vascularization of Engineered Tissues and its Application to Liver Organoids* *Oral Abstract Presentation:* **Pradyut Paul** *(US) – Pancreatic Stellate Cells Maintain Endocrine Islet Viability and Function in Vitro in a Laminin-Dependent Mechanism (Abstract 26)*
14:00-15:30	**17:00-18:30**	23:00-00:30	06:00-07:30	7:00-08:30	**IMMUNOTHERAPY & GENE THERAPY SESSION 4 – CELL THERAPY AND THE SPLEEN: MODULATING THERAPEUTIC OUTCOMES AFTER INFLAMMATORY CRISES OR INJURY ONSET** *Co-Chairs:* **Robert Mays** *(US)* & **Charles Cox** *(US)* *Speakers:* **Sangeeta Chavan** *(US) – The Neural Control of Immunity* **Richard Maziarz** *(US) – Potential Impact on Immune Effector Cell associated Cytokine Release Syndrome* **Sean Savitz** *(US) – Adult Cell Therapies and the Spleen Synergistically Provide Therapeutic Benefit Following Acute CNS Injury*
					REGULATORY SESSION 4 – GLOBAL REGULATORY PERSPECTIVES *Co-Chairs:* **Karen Nichols** *(US)* & **Dominic Wall** *(AU)* *Speakers:* **Scott Burger** *(US) – Regulatory Round Up* **Richard Snyder** *(US) – Viral Vector Quality - from Preclinical to First in Human* **Jessica Chery** *(US) – Regulatory Considerations for Gene Therapies incorporating Human Genome Editing* **Matthew Klinker** *(US) – Manufacturing Challenges During Accelerated Development of Cellular and Gene Therapy Products* *Session Sponsor:* cell therapies
15:30-15:45	**18:30-18:45**	00:30-00:45	07:30-07:45	08:30-08:45	**ISCT TV – WITH HOSTS KAREN NICHOLS** *(US)* **& DANIEL J. WEISS** *(US)* ISCT TV *Segment Sponsor* MaxCyte®

ON-DEMAND EDUCATION

LAB & CELL PROCESSING SESSION 1 – ISCT-AABB JOINT WORKING GROUP PROJECT UPDATES

Chair: **Michele Sugrue** *(US)*
Speakers:

Nadim Mahmud *(US) – Cryopreserved Hematopoietic Stem/ Progenitor Cells Stability Program-ISCT-AABB Joint Working Group: Stability Committee Project Update*
Wade Atkins *(US) – Update on ISCT-AABB Joint Working Group Project: An interpretive Tool For FDA HCTP Regulations*

LAB & CELL PROCESSING SESSION 2 – IMPACT OF COVID-19 ON THE PRACTICE OF THE CTL: GLOBAL PERSPECTIVES

Chair: **Joseph Schwartz** *(US)*
Speakers:

Julie Smolich *(US) – Impact of COVID-19 on Cellular Therapies: US Perspective*
Vicki Antonenas *(AU) – Cell Processing Laboratories & COVID-19: Challenges Confronted & Quality of Cryopreserved Cell Products. Experiences reported by Australia & New Zealand*
Yvette Tanhehco *(US) – COVID-19 Induced Changes to Cellular Therapy Operations: A NewYork-Presbyterian Hospital Perspective*
John Girdlestone *(UK) – Impact of COVID-19 on the Practice of the CTL: UK Perspective*

LAB & CELL PROCESSING SESSION 3 – QUALITY ASSESSMENT IN CELLULAR THERAPY – RISK ASSESSMENT, VALIDATIONS, AND AUDITS

Chair: **Lizette Caballero** *(US)*
Speakers:

Ronit Slotky *(US) – Quality Risk Management in Cellular Therapy*
Medhat Askar *(US) – Internal Audits: The What, How & When?*
Olive Sturtevant *(US) – Validation and Verification Protocols*

VETERINARY MEDICINES SESSION – PETS AND OWNERS, SAME WAY OF LIFE, SAME DISEASES! WHAT LESSONS MAY BE GAINED FROM MSCS APPLICATIONS TO PET POPULATIONS WITH NATURALLY OCCURRING DISEASES?

Chair: **Tracy Webb** *(US)*
Speakers:

Antonio José Villatoro *(ES) – Stem Cell Therapy in Veterinary: Preclinical Model for Human Medicine*
Nathalie Saulnier *(FR) – What Can We Learn from Trials with Companion Animals Affected with Osteoarthritis?*

COMMERCIALIZATION SESSION 5 – ANALYTICAL METHODS DEVELOPMENT: SUPPORTING PROCESS DEVELOPMENT AND MANUFACTURING FOR CLINICAL TRIALS AND COMMERCIALIZATION

Chair: **Scott Burger** *(US)*
Speakers:

William Janssen *(US) – Post Administration Immune Monitoring and Development of Potency Assays for Cell and Gene Therapies*
Magdalena Tary-Lehmann *(US) – Immunogenicity Assessment in Support of Gene Therapy Program – Use of ELISPOT*
Sarah Campion *(US) – Challenges and Solutions in Analytical Methods Development*

ISCT CHIEF SCIENTIFIC OFFICER ABSTRACT SHOWCASE

Chair: **Daniel Weiss** *(US)*
Oral Abstract Presentations:

Antonella Pinto *(US) – Derivation of Folliculogenic Organoids from Human iPSC (Abstract 1)*
Steve Oh *(SG) – Generation Of High Densities Of Universal O-ve Red Blood Cells From Human Induced Pluripotent Stem Cells In Bioreactors (Abstract 6)*
Sabiha Hacibekiroglu *(CA) – Engineered Safe and Immune-Tolerant 'Designer' RPE Cells Towards the Treatment of Age-Related Macular Degeneration (Abstract 5)*
Hyunjung Min *(US) – Mesenchymal Stromal Cells Reprogram Macrophages with Processing Bodies (Abstract 4)*
Andrea Mohr *(UK) – Fas-Threshold Signalling in MSCs Causes Tumour Progression and Metastasis (Abstract 3)*
Tom Wyrobnik *(SG) – Engineering Characterisation of A Novel Impeller For Use In Stirred-tank Bioreactors (Abstract 2)*

ADVANCED PRACTICE PROFESSIONALS SESSION 1 – COVID-19 THERAPIES AND COMPLICATIONS OF CAR T-CELL THERAPY

Chair: **Nicholas Szewczyk** *(US)*
Speakers:

Jeremy Ramdial *(US) – COVID-19 Treatments and Complications of Stem Cell Transplant and Cellular Therapy*
Bianca Santomasso *(US) – Management of Neurotoxicity in Cellular Therapy*
Sherry Adkins *(US) – CAR T-Cell Therapy: Long-Term and Late Effects*

ADVANCED PRACTICE PROFESSIONALS SESSION 2 – MODIFIED T-CELLS THERAPIES FOR HEMATOLOGIC MALIGNANCIES AND SOLID TUMORS

Chair: **Brian Primeaux** *(US)*
Speakers:

Partow Kebriaei *(US) – Driving CAR T cells in Hematologic Malignancies*
Parameswaran Hari *(US) – Dual Antigen Targeting in Lymphoma with CD20_19 Targeting*
David Hong *(US) – New Approaches with TCR for Solid Tumors*

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CORPORATE TUTORIALS

Hosted By:

IMPLEMENTATION OF ADVANCED QC TESTING SOLUTIONS FOR CELL AND GENE THERAPY MANUFACTURING

Co-Chairs: **Félix A. Montero Julian** *PhD, Healthcare Scientific Director, bioMerieux, FR,*
Rey Mali, *VP Sales and Marketing, Accellix, FR*
Speakers:
Irving Ford, *Head of CAR T QC laboratories, BMS, USA*
Rhessa Diaz, *Senior Principal Scientist, BMS, USA*

CHALLENGES IN SCALING ANALYTICS FOR CELL & GENE THERAPIES

Chair: **Colin Merrifield,** *Senior Strategic Product Manager, Simple Plex, Bio-Techne, USA*
Speakers:
Chris Heger, *Director, Application Science, Bio-Techne, USA*
Kiren Baines, *PhD, BioProcess Scientist, eXmoor Pharma Concepts, UK*

STREAMLINING DIGITAL TRANSFORMATION AND REDUCING DATA AND PROCESS SILOS IN BIOLOGICS

Chair: **John Conway**, *Chief Visioneer Officer, 20/15 Visioneers, USA*
Speakers:
Trent Carrier, *PhD, MBA, Chief Operating Officer, L7 Informatics, Inc., USA*
Steven Barash, *Director, Regulated IT, Cognate BioServices, USA*
Brennen Wright, *Field Application Scientist, L7 Informatics, Inc., USA*

STREAMLINING DIGITAL TRANSFORMATION AND REDUCING DATA AND PROCESS SILOS IN BIOLOGICS

Chair: **Jennifer Moody**, *Director Market Development Gene Therapy, Pall Corporation, CA*
Speakers:
Chris Ivimey, *Cell Culture Engineer I, Research and Development, Pall Corporation, USA*
Mark Schofield, *PhD, Senior R&D Manager, Research and Development, Pall Corporation, USA*
Emmanuelle Cameau, *Senior R&D Manager, Bioprocessing Research and Development, Pall Corporation, USA*

KEY CONSIDERATIONS IN SCALABLE REGENERATIVE MEDICINE MANUFACTURING PROCESS DEVELOPMENT AND NEXT GENERATION MSC3.0 PRODUCT FORMATS

Speakers:
Jon A. Rowley, *PhD, Founder & Chief Product Officer of RoosterBio Inc., USA*
Joseph Candiello, *PhD, Senior Product Manager of RoosterBio Inc., USA*

GLOBAL SHOWCASES

CORPORATE OVERVIEW

Global Showcase presented by:

EVERYTHING IS RETHINKABLE – ROBUST AND SCALABLE MANUFACTURE OF HUMAN CELLS VIA CELLULAR REPROGRAMMING

Presenter:
Mark Kotter, *MD, CEO & Founder bit.bio, Neurosurgeon, Stem Cell Biologist, UK*

WHAT'S NEXT FOR AAV-BASED GENE THERAPY?

Presenter:
Pascal Joly, *PhD, Principal, Catenion, Germany*

LOUISIANA-BASED CLINICAL PRODUCT MANUFACTURING FOR TISSUE REPAIR

Presenter:
Trivia Frazier, *PhD, MBA, President, CEO & Co-Founder of Obatala Sciences, Inc., USA*

VECTOR CONSTRUCTION FOR CELL AND GENE THERAPY

Presenters:
Thomas Jonsson, *PhD, Territory and Business Development Manager, VectorBuilder Inc., USA*
Vladimir Ivosev, *PhD, Sr. Territory Manager, VectorBuilder GmbH, Spain*
Stella Gideon, *Southeast & TX Sales Representative, VectorBuilder Inc., USA*

TECHNOLOGY APPLICATIONS	*Global Showcase presented by:*
SCALABLE XENO-FREE PRODUCTION OF MSC-DERIVED EVS IN SINGLE-USE BIOREACTORS ***Presenters:*** **Claudia Lobato de Silva,** *PhD, Assistant Professor, iBB, IST, University of Lisbon, PT* **Miguel de Almeida Fuzeta,** *PhD Candidate, iBB, IST, University of Lisbon, PT*	AventaCell BioMedical Corp
IDENTIFY AND SELECT OPTIMAL T CELL PHENOTYPES ***Presenter:*** **James Lovgren,** *Vice President of Cell Therapy, Berkeley Lights, USA*	BERKELEY LIGHTS
KEY CONSIDERATIONS FOR IMPLEMENTING RAPID MICROBIAL METHODS FOR MYCOPLASMA DETECTION ***Presenter:*** **Cynthia Martino,** *R&D Director, Bionique Testing Laboratories, Inc*	bionique Testing Laboratories
AUTOMATED CELL MANUFACTURING FOR RIGOR AND REPRODUCIBILITY IN PROCESS DEVELOPMENT AND PRODUCTION ***Presenter:*** **George Muschler,** *MD, Orthopaedic Surgeon & Clinician-Scientist at Cleveland Clinic, USA*	CELL X TECHNOLOGIES
THE CYMERUS™ IPSC-DERIVED MSC PLATFORM ***Presenter:*** **Kilian Kelly,** *MRPharmS, PhD, Chief Operating Officer, Cynata Therapeutics Limited, AU*	cynata therapeutics
STEM CELL-DERIVED EXOSOME PRODUCTION IN STIRRED-TANK BIOREACTORS ***Presenter:*** **Aurélie Tacheny,** *PhD, Application Specialist-Cell Handling, Eppendorf Application Technologies SA, BE*	eppendorf
CELL AND GENE THERAPY PRODUCT QUALITY WITH THE AURA CL ***Presenter:*** **Bernardo Cordovez,** *PhD, Chief Science Officer, Halo Labs, USA*	halo labs
HIGHLY MULTIPLEXED, SINGLE-CELL FUNCTIONAL PROTEOMICS OF CAR-T PRODUCTS ENABLES MORE PREDICTIVE PRODUCT CHARACTERIZATION, CELL MANUFACTURING OPTIMIZATION AND CELLULAR BIOMARKERS ACROSS PRODUCT TYPES ***Presenter:*** **Victor Tek**, *Product Manager, IsoPlexis, USA*	isoplexis
NEXT GEN CELL THERAPY MANUFACTURING WITH EKKO™ ACOUSTIC CELL PROCESSING SYSTEM ***Presenters:*** **Samantha Sbardella,** *Manager, Cell Therapy Manufacturing portfolio, Research Scientist Process/Product Development Application, MilliporeSigma, USA* **Robert Scott,** *Acoustic Cell Processing System portfolio, MilliporeSigma, USA*	MilliporeSigma
BIOREACTOR HYDRODYNAMIC CONDITIONS FOR UNIFORM CELL AGGREGATE FORMATION ***Presenter:*** **Maximilian Lee,** *IP & Marketing Manager, PBS Biotech, Inc., USA*	PBS BIOTECH
ALLOGENIC CELL THERAPY CRYOPRESERVATION PROCESS DEVELOPMENT AND OPTIMIZATION ***Presenter:*** **Brian Hawkins,** *PhD, Chief Technology Officer, Pluristyx, Inc., USA*	pluristyx™
KEY CONSIDERATIONS FOR HMSC PROCESS DEVELOPMENT ***Presenter:*** **Theresa D'Souza,** *PhD, Director, Development Services, RoosterBio, Inc., USA*	RoosterBio® Radically Simplifying Use of MSCs
150 MILLION-FOLD CUMULATED EXPANSION OF ENCAPSULATED HIPS CELLS IN BIOREACTOR ***Presenters:*** **Fabien Moncaubeig**, *Chief Development Officer at TreeFrog Therapeutics, France* **Maxime Feyeux,** *PhD, Chief Scientific Officer and Co-founder of TreeFrog Therapeutics, FR* **Kévin Alessandri,** *PhD, Chief Technology Officer and Co-founder of TreeFrog Therapeutics, FR*	TreeFrog therapeutics

MEDIA & REAGENTS

Global Showcase presented by: BioLegend® Enabling Legendary Discovery™

T & NK CELL CULTURE: NOVEL SUBSTITUTE FOR HUMAN AB SERUM

Presenter:
Vanda S. Lopes, *PhD, Scientist III, BioLegend, USA*

FUNCTIONAL MARKERS OF BONE MARROW DERIVED MESENCHYMAL STEM CELLS FOR ORTHOPEADIC APPLICATIONS

Presenter:
Martin J. Stoddart, *PhD, FRSB, AO, Research Institute (ARI), USA*

INTELLIGENT MEDIA DESIGN TO DRIVE BETTER THERAPEUTIC OUTCOMES

Presenter:
Brad Taylor, *PhD, VP of Marketing, Nucleus Biologics, USA*

MANUFACTURING SERVICES

Global Showcase presented by: BioCentriq™

BIOCENTRIQ CELL & GENE THERAPY DEVELOPMENT & MANUFACTURING CENTER

Presenter:
Haro Hartounian, *PhD, Senior Vice President and General Manager, BioCentriq, USA*

MANUFACTURING CONSIDERATIONS FOR MSCS AND BROADER ALLOGENEIC MODALITIES

Presenter:
Jef Pinxteren, *PhD, Director, Process and Analytical Development, Catalent Cell and Gene Therapy, USA*

DE-RISKING YOUR CAR-T MANUFACTURING PROCESS AND IMPROVING EFFICIENCY

Presenter:
Megan Logan, *BASc, MASc, Development Scientist, CCRM, CA*

MANUFACTURING CELL AND GENE THERAPY – COMMERCIAL SUPPLY VS HOSPITAL SUPPLY

Presenter:
Dominic Wall, *PhD, FFSc (RCPA), Interim CEO & Chief Scientific Officer, Cell Therapies Pty Ltd and Executive Director, Business Ventures, Peter MacCallum Cancer Centre, AU*

RESILIENCE – BUILDING THE WORLD'S MOST ADVANCED BIOPHARMACEUTICAL MANUFACTURING ECOSYSTEM

Presenter:
Rahul Singhvi, *ScD, MBA, Co-Founder and CEO, Resilience, USA*

DATA-DRIVEN SOLUTIONS TO UNDERSTAND AND MINIMIZE FAILURES OF CELL COLLECTIONS

DATA MANAGEMENT & LOGISTICS

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INTRODUCING THE MOST ADVANCED ULTRA COLD SHIPPER, CRYOPORT ELITE™

Presenter:
Lindsay Belcher, *Vice President, Business Development, Americas, Cryoport Systems, USA*

WELLSKY BIOTHERAPIES – SIMPLIFYING DATA MANAGEMENT FOR CELL AND GENE THERAPIES

Presenter:
Jonathan Wofford, *General Manager – Biotherapies, WellSky, USA*

HOW TO BUILD A CRYOGENIC LOGISTICS PLATFORM FOR ALLOGENEIC THERAPIES

Presenter:
Andrea Zobel, *Senior Director, Personalized Supply Chain, Would Courier, USA*

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bit.bio
THE CELL CODING COMPANY

Accelerated biomedical research, new generations of cures, increased global sustainability. These are in reach when biology transitions to engineering. At bit.bio, we work relentlessly to achieve this goal. We combine the concepts of coding and biology to provide human cells for research, drug discovery, and a new generation of medicines.

bit.bio

bluechiip®
Advancing Sample Management

Bluechiip understands that every biosample stored at low temperatures is critical. Managing them with optimal in quality in the most efficient way is the objective. Bluechiip is the only solution that provides sample temperature with ID in cryogenic environments to deliver confidence in every sample. Traditional tracking solutions are not keeping up with increased handling requirements of valuable samples. Bluechiip's unique and patented technology is designed to operate across a wide temperature range from -196°C up to 150 °C, creating the perfect system for managing sensitive biologics. Bluechiip Consumables, Readers and Software combine to provide an unparalleled ability to track and store sample level data, including temperature, across the cold chain process.

bluechiip.com

Brooks Life Sciences is a leading provider of life science sample-based solutions. As a service provider to labs around the world, Brooks Life Sciences offers a full suite of reliable cold-chain sample management solutions and genomic services across areas such as drug development, clinical research, and advanced cell therapies for the industry's top pharmaceutical, biotech, academic, and healthcare institutions globally. Brooks Life Sciences' GENEWIZ division is a leading provider of DNA gene sequencing and gene synthesis services. The organization is headquartered in Chelmsford, MA, with operations in North America, Europe, and Asia.

brookslifesciences.com

The Burroughs Wellcome Fund serves and strengthens society by nurturing a diverse group of leaders in biomedical sciences to improve human health through education and powering discovery in frontiers of greatest need.

BWF's financial support is channeled primarily through competitive peer-reviewed award programs.

bwfund.org

Cabaletta is developing targeted, engineered T cell therapies for patients with B cell-mediated autoimmune diseases, designed to provide potential cures by eliminating pathogenic B cells expressing autoantibodies, while sparing the normal B cells.

cabalettabio.com

Carisma Therapeutics is pioneering the development of CAR macrophages, a disruptive approach to immunotherapy. Our technology leverages advances in macrophage biology, chimeric antigen receptor engineering and adoptive cellular therapy for the treatment of human disease.

carismatx.com

Catalent Cell & Gene Therapy is a full-service partner for adeno-associated virus (AAV) vectors and CAR-T immunotherapies, with deep experience in viral vector scale-up and production. Catalent recently acquired MaSTherCell, adding expertise in autologous and allogeneic cell therapy development and manufacturing to position Catalent as a premier technology, development and manufacturing partner for innovators across the entire field of advanced biotherapeutics. Catalent has a global network of clinical and commercial manufacturing facilities, and fill-finish and packaging capabilities located in both the U.S. and Europe. Catalent Cell & Gene Therapy has produced more than 100 cGMP batches across 70+ clinical and commercial programs.

catalent.com

Catenion is a science-driven strategy consultancy focused on biomedical innovation with a proven track record of creating value for clients and patients.

catenion.com

CCRM, a global public-private partnership headquartered in Canada, is funded by the Government of Canada, the Province of Ontario, and leading academic and industry partners. It supports the development of regenerative medicines and associated enabling technologies, with a specific focus on cell and gene therapy. A network of academic researchers, leading companies, strategic investors and entrepreneurs, CCRM accelerates the translation of scientific discovery into new companies and marketable products for patients, with specialized teams, funding and infrastructure. CCRM sources and evaluates intellectual property from around the globe, offers various consulting services, conducts development projects with partners, and establishes new companies built around strategic bundles of intellectual property. CCRM has a fully resourced research facility used to both evaluate and advance technologies, a centre for process development and advanced manufacturing, and a GMP facility within a 40,000 square foot space. CCRM is the commercialization partner of the University of Toronto's Medicine by Design. CCRM is hosted by the University of Toronto and was launched in Toronto's Discovery District on June 14, 2011.

ccrm.ca

The Cell and Gene Therapy Catapult was established as an independent centre of excellence to advance the growth of the UK cell and gene therapy industry, by bridging the gap between scientific research and full-scale commercialisation. With more than 300 employees focusing on cell and gene therapy technologies, it works with partners in academia and industry to ensure these life-changing therapies can be developed for use in health services throughout the world. It offers leading-edge capability, technology and innovation to enable companies to take products into clinical trials and provide clinical, process development, manufacturing, regulatory, health economics and market access expertise. Its aim is to make the UK the most compelling and logical choice for UK and international partners to develop and commercialise these advanced therapies. The Cell and Gene Therapy Catapult works with Innovate UK.

catapult.org.uk

Cell Therapies Pty Ltd is a contract development and manufacturing organization (CDMO) that manufactures and deploys advanced cell-based therapies to the global market. Established in 2003, Cell Therapies Pty Ltd is one of the most experienced cGMP compliant manufacturers for cell therapies, gene therapies, cellular immunotherapies and regenerative medicine products globally. Working closely with its clinical and research collaborators at the Peter MacCallum Cancer Centre (http://petermac.org), Cell Therapies Pty Ltd provides its clients with needle-to-needle solutions for apheresis collection, GMP manufacturing, cryopreservation, state of the art imaging (real-time in vivo cell tracking) and clinical trial implementation. Cell Therapies Pty Ltd has a ten (10) clean room GMP facility located in Melbourne, Australia at the heart of the biomedical precinct, with access to hospitals, research institutes and universities to support development, translation and patient access. This facility holds both clinical trial and commercial supply manufacturing licenses from the Australian Therapeutic Goods Administration (TGA), ensuring the products from our facility meet global regulatory standards. We have a proven track record of delivering cell-based therapeutic products to patients from early phase clinical trials through to commercial supply according to the requirements of local and international regulators. We have also established multi continental manufacturing networks to support trials concurrently registered in Europe, Asia and North America and have an enviable track record for efficient and successful tech transfer inbound and outbound to our collaborators.

celltherapies.com.au

Founded as a Delaware Corporation in 2017, Cell X Technologies, Inc. is a spin-out of the Cleveland Clinic by stem cell scientist and Orthopedic Surgeon, Dr. George Muschler. The Company's initial product, "Cell X", is an automated robotic cell processing platform, designed and engineered in collaboration with Parker Hannifin Corporation. The Cell X Automation System builds on this platform and integrates automated large-field-of-view microscopic imaging, image

analysis, atraumatic cellular picking and placing, cell culture media changes, plate handling and storage for up to 500 plates, all within an environmentally controlled and isolated GMP-capable system. What makes this system stand out from the crowd is its comprehensive data acquisition, annotation, and documentation of cell source provenance, processing interventions and performance outcomes. This satisfies regulatory requirements and provides quantitative feedback for process development.

cellxtechnologies.com

CELLBOX

Cellbox Solutions is a young technology company developing and marketing innovative logistics solutions for the BioMedTech, Pharmaceutical and Academic sectors.

Our flagship product, the Cellbox portable CO2 incubator, offers the unique opportunity to incubate and cultivate cells during transport - saving time & effort - while maintaining high cell viability and improving the outcome of downstream applications and assays.

cellbox-solutions.com

CellGenix

High Quality GMP Reagents for Cell and Gene Therapy Manufacturing. CellGenix is a leading global supplier of high quality raw materials for the expanding cell and gene therapy and regenerative medicine space. We develop, manufacture and market human cytokines and growth factors in preclinical and GMP quality along with GMP serum-free media for further manufacturing of ATMPs. Our products are used by academia and industry partners in clinical trials and commercial manufacturing throughout the world.

With 25 years of experience we are experts in the GMP manufacturing of raw materials for the cell and gene therapy space. As a former ATMP developer and manufacturer we gained in-depth cell culture knowledge and superior regulatory expertise. With this unique background we understand the high requirements our customers face during product development and the regulatory approval process. By offering expert technical and regulatory support we can help simplify raw material qualification and validation efforts. CellGenix operates a state-of-the-art GMP facility for production of recombinant proteins and cell processing in Freiburg, Germany. A subsidiary is located near Boston in Portsmouth, NH/USA.

Safe • GMP Compliant • Reliable

cellgenix.com/covid-19-update/

CELLVEC

CellVec is a specialist provider of custom viral vectors for pre-clinical and clinical applications. We are a gene therapy Contract Development and Manufacturing Organisation (CDMO) that specialises in research, translational development and GMP manufacturing of gene transfer vectors.

cellvec.com

cryoport systems

Cryoport is the life sciences industry's most trusted provider of temperature-controlled supply chain solutions, serving biopharmaceutical, IVF and surrogacy and animal health organizations around the world. Cryoport's proprietary Cryoport Express® liquid nitrogen dry vapor shippers, innovative C3™ 2-8°C solution, Cryoportal® logistics management platform, leading-edge Smartpak II® condition monitoring system and geo-sensing technology paired with unparalleled cold chain expertise and 24/7/365 customer support, make Cryoport the end-to-end supply chain partner that you can trust.

cryoport.com

CURIOSIS
Bioengineering and Life Science

Curiosis is an innovative biotech company to provide integrated solutions in the field of Life science, especially in cell-based application.

curiosis.co.kr

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors. Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. Clinical trials of Cymerus MSCs in osteoarthritis (Phase 3) and in severe complications arising from COVID-19 (Phase 2) are currently ongoing. Planning is also underway for further clinical trials of Cymerus MSCs in GvHD (through licensee Fujifilm), critical limb ischemia, idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

cynata.com

Cytiva is a global provider of technologies and services that help advance and accelerate the development and manufacture of therapeutics. Previously GE Healthcare Life Sciences, Cytiva's diverse portfolio includes well-recognized brands such as ÄKTA, Amersham, Biacore, FlexFactory, HyClone, MabSelect, Whatman and Xcellerex. Cytiva brings speed, efficiency and capacity to research and manufacturing workflows, enabling the delivery of transformative medicines to patients.

cytiva.com

Ecolab Life Sciences supports safety, compliance and operational efficiency for pharmaceutical and personal care manufacturers by delivering a comprehensive, programmatic approach and global expertise to contamination control, cleaning and disinfection. Our end-to-end solutions, enhanced by Bioquell technology, allow our customers to have safer products and processes by reducing their risks.

ecolab.com/lifesciences

Bioprocess solutions for various industries and applications Bioprocess engineers develop and produce a multitude of products and ingredients available today. Their applications are diverse, and the products can be found in pharmaceutical, chemical, and nutrition industries. With an integrated portfolio comprising software, instruments, consumables, and services, Eppendorf can satisfy the demands of bioprocess development through production. In that way and in line with our corporate mission, we contribute to the efforts of Eppendorf customers worldwide to improve human living conditions.

eppendorf.com

Esco Aster is a contract development and manufacturing organisation (CDMO) focusing on offering vaccine-, bio-, cell- and gene-therapy development manufacturing services using primarily its proprietary adherent Tide Motion platform supplemented by single use suspension and fermentation, downstream bioprocessing, and custom bioengineering equipment for client specific therapeutics. Within the in vitro/in vivo Dx space we focus on developing mAb-based antigens, single domain antibodies for radioimaging, RT-PCR reagents, RCL diagnostics. We work with collaborators to provide turnkey mobile Dx labs Aster Xpress™. Within the chem- biopolymer- cosmetic, personal

care, cosmeceutical- segments, we excel in converting batch processes into continuous flow chemistry, closed aseptic processing within isolators and variety of skin safety/efficacy testing services. For the COVID-19 pandemic, we are working on an end to end trace, test, and treat platform from swab booths, to mobile labs, turnkey modular screening, and treatment centres with isolation rooms as well as working on Dx, therapeutics and vaccines.

escoaster.com

eurofins | VRL

With over 35 years of experience in donor testing, VRL Eurofins has a national reputation for its expertise in providing comprehensive laboratory services to meet the unique testing needs of the transplant and cell therapy communities.

Our high complexity testing laboratories offer Donor Eligibility Screening, HLA/Immunogenetics and Microbiology Testing, using the most appropriate regulated testing technologies for the transplant and medical communities. Eurofins VRL offers a robust Quality Program- FDA-registered for HCT/Ps, certifications, licenses and accreditation's for CLIA, State Agencies, ASHI, Therapeutic Goods Administrations (TGA), German Health Authority.

VRL Eurofins cell donor HCT/P regulated testing for all donor suitability and eligibility determination requirements. We offer all testing under one lab for ease of result reporting, customer support, IT integration and logistics.

vrl-eurofins.com

Fact FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

FACT establishes standards for high quality medical and laboratory practice in cellular therapies. FACT is a non-profit corporation co-founded by the International Society for Cell and Gene Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT) for the purposes of voluntarily inspection and accreditation in the field of cellular therapy.

factwebsite.org

FUJIFILM IrvineScientific

As a cell culture media pioneer, we leverage decades of industry insight to deliver advanced cell culture media solutions for use in regenerative medicine, biopharmaceuticals, reproductive medicine, medical and translational research, and clinical diagnostics. Our innovative products and services enable scientists to fulfill the potential of emerging therapies and help clinicians achieve successful outcomes for their patients.

irvinesci.com

G-CON MANUFACTURING Inc.

G-CON Manufacturing designs, builds and installs prefabricated cleanrooms called PODs®. Our mission is to respond to customer requirements with speed, diligence and dedication, thereby achieving the best possible cleanroom solution with the most attractive total cost of ownership to enable affordable treatments for every patient. G-CON's POD portfolio provides cleanrooms in a number of dimensions for a variety of uses, from laboratory environments to personalized medicine and production process platforms. G-CON POD cleanrooms surpass traditional cleanroom structures in scalability, mobility and the possibility of repurposing once the production process reaches its lifecycle end.

gconbio.com

halo labs

Halo Labs has the ultimate product quality tools for cell and gene therapy. The Aura and Aura CL, can count and characterize cell and viral vector aggregates, differentiate them from other aggregates, quantify subvisible particles, and ID contaminants in your product. A simple, plate-based approach enables low-volume (5µL), high-throughput, fully automated imaging and analysis at any stage from developability assessment through quality control.

halolabs.com

Harro Höfliger specializes in the development of customer-oriented process and production solutions for pharmaceutical and medical applications as well as market-oriented consumer products. In addition to innovative machine platforms and packaging machines, customized turnkey system solutions for product assembly, processing of web materials, as well as dosing and inhalation technology are the company's core expertise. Furthermore, Harro Höfliger offers extensive services related to process development. A team of experts conducting process capability analyses of active ingredient containing substances under real conditions, supports customers in recipe optimization or the manufacturing of stability samples. They have special expertise in the processing of powder materials for inhalative and solid administration forms, as well as in the design of GMP-compliant production conditions for both solid and liquid products. The systematically structured portfolio of upscalable test machines and modules, as well as requirement-oriented technology platforms, results from many years of experience and targeted research and development. Thus, Harro Höfliger covers all phases from the laboratory stage to high-performance production. Together with their Excellence United partners, a strategic alliance of five leading machine and system manufacturers, Harro Höfliger offers customers cutting-edge technology and a global sales and service network.

hoefliger.com

HemaCare, a Charles River company, is a global leader in the supply and customization of human-derived biological products and services for biomedical research, drug discovery, and cellular therapy process development. Through our network of collection centers with access to an extensive recallable and reliable donor network, we provide clients with the cellular material they need for the development of the next generation of cell and gene therapies – including fresh and cryopreserved starting material and isolated cellular material derived from peripheral blood, bone marrow, and cord blood. Combined with Charles River's integrated, early-stage portfolio of discovery, safety assessment, and manufacturing support services, we provide customers comprehensive solutions from discovery through commercialization.

hemacare.com

ICCBBA is the not-for-profit, nongovernmental international standards organization responsible for the management and development of the ISBT 128 Standard. Used in more than 85 countries across six continents and disparate health care systems, ISBT 128 is the global standard for the terminology, identification, coding, and labeling of medical products of human origin including blood, cell, tissue, milk, and organ products. The Standard has been designed to ensure the highest levels of accuracy, safety, and efficiency for the benefit of donors and patients worldwide.

iccbba.org

The International Society for Extracellular Vesicles is the leading professional society for researchers and scientists involved in the study of microvesicles and exosomes. With nearly 1,000 members, ISEV continues to be the leader in advancing the study of extracellular vesicles. Founded in 2012 in Sweden, ISEV has since moved its Headquarters to the United States. Through its programs and services, ISEV provides essential training and research opportunities for those involved in exosome and microvesicle research.

www.isev.org

IsoPlexis is a life science technology company building solutions to accelerate the development of curative medicines and personalized therapeutics. Our award-winning single-cell proteomics systems reveal unique biological activity in small subsets of cells, allowing researchers to connect more directly to in vivo biology and develop more precise and

personalized therapies. Our integrated systems – named as a top innovation or design by the Scientist Magazine, Fierce, BIG Innovation and Red Dot, among others – are used globally to advance the field of single-cell biology into new 'omic possibilities as our customers generate solutions to overcome the challenges of complex diseases and therapeutics. Our products have been adopted by researchers around the world, including 15 of the top 15 global pharmaceutical companies and by approximately 45% of comprehensive cancer centers.

isoplexis.com

L7INFORMATICS

The L7 mission is to revolutionize the scientific process by streamlining process and data management thereby accelerating precision health across life sciences, healthcare, and food value-chains. L7 Informatics provides software and services that enable digital transformation for scientific research and development

l7informatics.com

Lonza

We provide contract development and manufacturing services that enable pharma and biotech companies to deliver medicines to patients. From the building blocks of life to the final drug product, our solutions are created to simplify your outsourcing experience and provide a reliable outcome when you expect it. Our extensive track record includes commercialization of pioneering therapies and manufacturing of a wide variety of therapies. Together, we can bring the next medicine to life.

pharma.lonza.com/offerings/cell-and-gene-therapies

LOUISIANABIO

Louisiana Bio is an independent, non-profit 501(c)(6) trade association whose mission is to be the voice of Louisiana's life sciences industry and research organizations in the biosciences, pharmaceuticals, medical technology (devices and diagnostics), health IT and bio-agriculture sectors.

louisianabio.org

LYKAN BIOSCIENCE

Lykan Bioscience is a privately held, cell therapy focused, contract development and manufacturing services organization. Based on their decades of biopharmaceutical industry experience, the Lykan team offers a full range of services for cell-based therapies from clinical production to commercial manufacture. Located in Hopkinton, MA, the company's SMART Manufacturing™ purpose-built facility was uniquely designed to fully integrate cGMP principles and advanced software solutions. Our software application platform allows for timely access to data, logistics, and expertise in driving life-saving treatments.

lykanbio.com

MaxCyte®

MaxCyte is a leading provider of cell-engineering platform technologies driving the next-generation of cell-based therapies. The Company's technology is employed by leading drug developers, including all of the top ten global biopharmaceutical companies. MaxCyte has granted 12 strategic platform licenses to leading cell-based therapy developers. Through 2020, MaxCyte has granted licenses for more than 140 cell therapy programs, with 100+ licensed for clinical use. Our Flow Electroporation® technology and next-generation ExPERT® platform enable our partners to accelerate, streamline and improve the drug development process. MaxCyte was founded in 1998 and is headquartered in Gaithersburg, Maryland, U.S.

maxcyte.com

Mill Creek Life Sciences is the first company to commercialize human platelet lysate for cellular therapy. We offer a range of hPLs for all your cell therapy needs.

millcreekls.com

Cell and gene therapies hold the promise to change lives. Even as the path to patients accelerates, manufacturing and regulatory complexity remains a challenge. With limited process templates, evolving regulatory guidance, and urgent patient needs, finding a partner with experience is critical to success. Our company is giving shape to cell and gene therapy development every day. We bring 30+ years of expertise, and a global organization to integrate leading manufacturing technologies with process development, scale-up, safety testing, and regulatory knowledge to meet your therapy's needs. We have more experience in this area than almost anyone else in the industry. We were the first gene therapy CDMO to produce commercial product following successful regulatory inspection. Our products and services include optimized manufacturing platforms, media and reagents; manufacturing, biosafety and characterization testing, and process development services. Draw on our experience to bring your cell and gene therapies to life.

sigmaaldrich.com/genetherapymanufacturing

Miltenyi Biotec is a global provider of products and services that advance biomedical research and cellular therapy. Our innovative tools support research at every level, from basic research to translational research to clinical application. Used by scientists and clinicians around the world, our technologies cover techniques of sample preparation, cell isolation, cell sorting, flow cytometry, and cell culture. Our 30 years of expertise spans research areas including immunology, stem cell biology, neuroscience, and cancer. Today, Miltenyi Biotec has about 3,000 employees in 28 countries – all dedicated to helping researchers and clinicians make a greater impact on science and health.

miltenyibiotec.com

MVE Biological Solutions is the leading global manufacturer of vacuum insulated products and cryogenic systems. Over 50 years, we set the standard for storage of biological materials at low temperatures. Today, MVE continues to exceed these standards. Industries from around the world look to MVE for excellence and innovation. Our solutions empower industries to better utilize cryogenic technology. In this manner, MVE continues to make a vital contribution in today's biomedical Life Sciences industry. The MVE range of cryogenic freezers and aluminum dewars have been engineered for ultimate reliability and maximizing hold times at the ultra-low temperatures vital to the preservation of critical human and animal tissues and vaccines. MVE is the preferred brand for cryogenic equipment in a variety of application areas including bio-pharma cell and gene therapies, storage of cord blood and stem cells, medical research facilities, government institutions, IVF centers, hospitals and clinics, and animal husbandry and livestock.

MVEbio.com

Nordmark is a pharmaceutical company which develops and produces ingredients and drug products through all stages of the value chain. As the world's largest manufacturer of pharmaceutical collagenase, we are able to provide translational enzymes - research and GMP Grade collagenase and neutral protease products – to simplify the path from research to clinic. Our Nordmark Biochemicals division offers products for nearly every cell isolation application, including our highly-purified, animal-free Collagenase AF-1 GMP Grade and our excellent Collagenase NB 6 GMP Grade for stem cell isolation. Supporting documentation and access to Drug Master Files are available.

nordmark-biochemicals.com

NOVARTIS

Novartis is reimagining medicine to improve people's lives. We use innovative science and digital technologies to create transformative treatments. Novartis products reach more than 800 million people globally and we are finding innovative ways to expand access to our medicines. About 109,000 people of more than 145 nationalities work at Novartis.

novartis.com

Nucleus Biologics

Nucleus Biologics, The Cell Performance Company, is the leading provider of custom cell-growth media, tools, and technologies for cell and gene therapy. Their mission is to speed the time from scientific discovery to cure by delivering innovative, transparent and cGMP products and services with the goal of disrupting the market and eliminating antiquated practices and products. Current off the shelf media providers guard their proprietary formulations requiring manual manipulation of purchased media for optimization of Critical Quality Attributes (CQAs) that can impact the potency of cell therapies. These modifications also impact the scalability of processes which can facilitate a smoother transition to a commercialized cellular therapy. Nucleus Biologics' products provide a consistent, proven supply chain that eliminates variability and returns ownership of cell culture media formulations back to their customers. They can provide both guided and automated formulation services through their proprietary AI-driven algorithms that instantaneously canvas thousands of peer-reviewed publications to assist in the formulation of custom media for their customer's specific cell type and CQAs. Formulations generated by their customers belong solely to those customers and can be scaled to meet their specific requirements. This provides a consistent source of cGMP-compliant media tailored to the needs of their customers development programs that can scale from bench to bioreactor.

nucleusbiologics.com

Obatala

Obatala Sciences is a biotechnology toolkit company based in New Orleans, LA that provides products and services to researchers in the fields of regenerative medicine, tissue engineering, metabolic diseases, and oncology. We offer human-derived hydrogels, mesenchymal stem cells, and cell culture media and provide in vitro research on our ObaCell™ Adipose-on-a-Chip system and in vivo research on our proprietary pressure ulcer model.

obatalasciences.com

OrganaBio

OrganaBio, LLC is a privately held solutions provider for the cell, gene, and immunotherapy fields. OrganaBio's company philosophy and portfolio is founded in the belief that supply chain control, quality and redundancy ultimately dictate program success. As such, OrganaBio has established a proprietary supply chain of perinatal tissue from non-compensated donors and offers the industry a range of cells from these tissues including MSCs, HSCs, NK and T cells. OrganaBio currently manufactures RUO cellular starting materials for allogeneic cell therapy development and is building cGMP manufacturing capabilities (Miami, FL; Q3 2021) to provide cGMP cells to the industry and to address the industry's need for readily accessible cleanrooms.

organabio.com

OriGen BIOMEDICAL

OriGen Biomedical supplies a complete line of single use disposable products for use in Regenerative Medicine applications including T-Cell therapies. Our products are FDA-cleared, MDSAP-certified, CE-marked, cGMP-manufactured, and ISO 13485:2016 certified. The PermaLife Cell Culture Bag is an optimal way to protect critical cell cultures. PermaLife has a user-inspired design including a needle-free, luer-actuated adapter which is self-sealing to make it easy to sample, feed, and harvest sensitive cells. The PermaLife is also gas

permeable and water impermeable which eliminates the need for a humidified incubator. The CryoStore™ Freezing Bag is the industry-preferred cryogenic freezing bag. The CryoStore™ Bag is available in a variety of configurations including a number of tubing and multi-bag options, allowing you to select the product that best fits your process. The CryoStore™ Multi-Chamber Freezing Bag allows for cryopreservation of small volume blood components for future regenerative medicine applications. Multiple chambers are filled simultaneously through the channel at the bottom of the bag. The individual 4-6mL chambers allows for multiple post thaw applications. CryoPur™ DMSO Solutions are certified to USP and Ph. Eur. Standards. CryoPur, CryoPur-D, CryoPur-S, and CryoPur-T Solutions come sterile, aseptic filtered and are non-pyrogenic. CryoPur™ Solutions are available as 100% DMSO and a DMSO Dextran mixture. OriGen supplies CryoPur™ in vials and syringes to meet your organization's needs. OriGen is known for its customer-driven product development process where OriGen can adapt its products to better fit laboratories' protocols, not force labs to change protocols to match OriGen's products. Visit https://www.origen.com/customer-driven-product-development-process for more information.

origen.com

PALL

Pall Biotech can provide fully integrated bioprocessing solutions for gene therapy, from discovery through to commercialization; from upstream through to final filling; from initial design through to implementation. With a range of solutions covering multiple virus types and with production in either adherent of suspension processes, our extensive single-use portfolio can offer you the complete solution you need.

PBS BIOTECH®

PBS Biotech produces the most advanced single-use bioreactors for the rapidly emerging cell therapy market. We also offer contract research and process development services, with industry-leading knowledge of a variety of cell therapy applications.

pbsbiotech.com

Penn Medicine

Penn Medicine, part of the world-renowned University of Pennsylvania, is at the forefront of cell and gene therapy. We discover treatments and cures that drive medical innovation, deliver state-of-the-art care and provide personalized medicine.

pennmedicine.org

phasetwo

Phase Two Cold Chain Solutions enables the critical infrastructure in packaging, storage, shipping, and monitoring of samples that require cold storage. Dry shippers, control rate freezers, cryogenic preservation, and on demand dry ice production. Phase Two provides the equipment necessary for laboratories, pharmaceutical, universities, and research centers globally. Phase Two is a Tomco Systems wholly owned subsidiary.

tomcosystems.com/phasetwo

pluristyx™

Pluristyx, Inc. is an advanced therapy tools and service company serving customers in the rapidly growing field of regenerative medicine and cellular therapies. Pluristyx has a line of pluripotent stem-cell based products and also offers contract development, manufacturing, and consulting services.

pluristyx.com

Protide PHARMACEUTICALS

Protide Pharmaceuticals, Inc. is a fully integrated organization devoted to discovery, development and the advancement of technologies and processes in clinical cell therapy, regenerative medicine, transplantation and cell engineering. With over 35 years of innovative products and services, and hundreds of clinical trials using our technology, we positively

impact science through knowledge. Inspired by the scientists, patients, and physicians we support, Protide continues as an entrepreneurial, science driven organization.

protidepharma.com

RESILIENCE

Resilience (National Resilience, Inc.) is a first-of-its-kind manufacturing and technology company dedicated to broadening access to complex medicines and protecting biopharmaceutical supply chains against disruption. Founded in 2020, the company is building a sustainable network of high-tech, end-to-end manufacturing solutions to ensure the medicines of today and tomorrow can be made quickly, safely, and at scale.

resilience.com

Roche

Roche CustomBiotech offers high-quality solutions and documention delivering real value in various cell and gene therapy manufacturing workflow steps from cell isolation to quality control release testing customizable to meet your needs.

roche.com

RoosterBio®
Radically Simplifying Use of MSCs

RoosterBio, Inc. is a privately held cell manufacturing platform technology company focused on accelerating the development of a sustainable Regenerative Medicine industry, one customer at a time. RoosterBio's products are high-volume, affordable, and well-characterized adult human mesenchymal stem/stromal cells (hMSCs) paired with highly engineered media systems. RoosterBio has simplified and standardized how living cells are purchased, expanded, and used in development, leading to marked time and costs savings for customers. RoosterBio's innovative products are ushering in a new era of productivity and standardization into the field.

roosterbio.com

ScaleReady

ScaleReady is a joint venture between Bio-Techne, Fresenius Kabi, and Wilson Wolf. Bringing together proven tools and technologies for cell culture, cell activation, gene editing, and cell processing, ScaleReady provides leading therapeutic developers with the most simple, scalable, and versatile manufacturing platform in the industry. Our platform includes G-Rex® cell culture technology, the Lovo and Cue cell processing systems, and a wide range of GMP proteins, reagents, media, and gene editing technologies.

SEXTON
BIOTECHNOLOGIES

Sexton Biotechnologies is a company focused on the development and sales of bioproduction tools for cell and gene therapy founded in 2019, located in Indianapolis, IN. Sexton develops purpose-built CGT tools and media to enable flexible automation and scaling of cell manufacturing processes to increase the probability of positive clinical outcomes and reduce time-to-market, failure points, and labor costs. Sexton's portfolio includes the CellSeal platform of cryo-storage tools and fill/finish systems and human platelet lysate growth supplements.

sextonbio.com

SINFONIA

Automatic cell culture device – Our system is equipped with Process Analytical Technology (PAT) to monitor culture status in real time, and stabilizes process by automation; these enable us to manufacture cell products based on QbD concept.

sinfo-t.jp

STEM CELL NETWORK 20 YEARS RÉSEAU DE CELLULES SOUCHES

Celebrating 20 years, the Stem Cell Network (SCN) is a national non-profit that supports stem cell and regenerative medicine research, training the next generation of highly qualified personnel, and delivering outreach activities across Canada. SCN's goal is to advance science from the lab to the clinic for the benefit of Canadians. SCN has been supported by the Government of Canada since inception in 2001. This strategic funding, valued at $118M, has benefitted approximately 196 world-class research groups and 3,300 trainees and has catalyzed 24 clinical trials. Powering research for better health.

stemcellnetwork.ca

TECHNOFLEX

Over 45 years of experience have made Technoflex an innovative firm, as well as a European leader in the design and manufacture of flexible bags and connectors for the pharmaceutical industry. Our cutting-edge technology and internal R&D resources enable us to provide customized, reliable and easy-to-use solutions. Our proficiency in the pharmaceutical primary packaging of injectable drugs and cell culture, allow us to produce innovative containers matching strong AQL level within our clean room ISO 7 (Class 10000. Technoflex also develops a high capacity working with all-kind flexible films, which may be subject to high thermal amplitudes and to permeability. As for cellular therapy, Technoflex provides state-of-the-art bags (SafeCell® and Cryocell®) delivering high value in the areas of: Ex-vivo Cell Culture, Development of Cell Therapy treatment, Blood Derivatives, Cryopreservation of cord blood & stem cells, Organ preservation. Our range of FEP bags SafeCell®, developed with a specific leak-proof design, offers optimal traceability. Recently Technoflex has released his new primary packaging Dual-Mix® for the reconstitution of unstable molecules. Technoflex' s flexible containers are compliant with the US & EU pharmacopoeias (EP 3.1.3 & EP 3.1.6 / 21CFR 77.18.10 / USP class VI; FDA DMF #19057; DMF #032647; Canada DMF #2007-070)

technoflex.net

TERUMO BLOOD AND CELL TECHNOLOGIES

Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions.

Our employees around the world believe in the potential of blood and cells to do even more for patients than they do today.

terumobct.com

TMUNITY™

Tmunity is a unique biotherapeutics company because of the unrivaled depth of its scientific founders' and management team's experience and demonstrated field-specific track record, its mastery of the application of gene-editing and cell engineering tools in human trial settings, the maturity of its clinic-ready development programs, the readiness to scale through its manufacturing processes and facility, and the breadth of its relevant clinical, regulatory, commercial and company-building expertise.

tmunity.com

JSRM

The Japanese Society for Regenerative Medicine (JSRM) is an academic organization that covers all aspects of stem cell research, gene cell therapy, and tissue engineering, with many countries organizing their own academic groups, and has over 6,000 members consisting of basic researchers, clinicians, engineers, and ELSI experts. JSRM's activities are not limited to the exchange of research results, such as holding academic meetings and publishing journals, but also include a wide range of national projects, such as clinical research support, human resource development, promotion of industry-academia collaboration, and public and patient

Involvement. From FY2021, we are expanding our activities to include free support for companies that are unable to conduct clinical trials in Japan on their own, and the provision of video materials on cell processing for a fee.

jsrm.jp

ThermoFisher SCIENTIFIC

Thermo Fisher Scientific is positioned to provide the quality materials, services & support needed to accelerate advanced therapy development. Partner with us to access the high-quality materials, services & support you need from discovery to clinical research and commercial manufacturing. Through our Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, Patheon, & Gibco brands, we offer unmatched technologies, manufacturing & distribution capabilities.

thermofisher.com/cgt

TreeFrog therapeutics

TreeFrog Therapeutics is a stem cell company that will enable millions of patients to access the medical revolution of cell therapies by overcoming current critical manufacturing issues. TreeFrog Therapeutics has developed C-Stem® : a proprietary technology platform that provides an end to end 3D scalable solution that will dramatically reduce treatment costs. Through strategic partnership and co-developments, TreeFrog Therapeutics will help cell therapy players to secure cell production and quality, fasten clinical development and facilitate market access.

treefrog.fr

VectorBuilder

As a global pioneer in custom DNA vectors and recombinant viruses, VectorBuilder's revolutionary online-to-offline (O2O) platform provides a powerful one-stop solution to all the vector and virus needs in the life sciences. VectorBuilder has a wide spectrum of offerings, including: Vector design, Custom cloning, Virus packaging, Library construction, BAC recombineering, Mutagenesis, Stable cell line generation, Covid-19 coronavirus solutions and GMP manufacturing.

vectorbuilder.com

VERTEX
THE SCIENCE of POSSIBILITY

Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has multiple approved medicines that treat the underlying cause of cystic fibrosis (CF) — a rare, life-threatening genetic disease — and has several ongoing clinical and research programs in CF. Beyond CF, Vertex has a robust pipeline of investigational small molecule medicines in other serious diseases where it has deep insight into causal human biology, including pain, alpha-1 antitrypsin deficiency and APOL1-mediated kidney diseases. In addition, Vertex has a rapidly expanding pipeline of genetic and cell therapies for diseases such as sickle cell disease, beta thalassemia, Duchenne muscular dystrophy and type 1 diabetes mellitus.Founded in 1989 in Cambridge, Mass., Vertex's global headquarters is now located in Boston's Innovation District and its international headquarters is in London. Additionally, the company has research and development sites and commercial offices in North America, Europe, Australia and Latin America. Vertex is consistently recognized as one of the industry's top places to work, including 11 consecutive years on Science magazine's Top Employers list and a best place to work for LGBTQ equality by the Human Rights Campaign. For company updates and to learn more about Vertex's history of innovation, follow us on Facebook, Twitter, LinkedIn, YouTube and Instagram.

vrtx.ca

Vineti

Vineti creates the essential software solution to drive and scale personalized therapies, such as cell and gene therapy. Our leading Personalized Therapy Management (PTM®) platform delivers simplicity, compliance, and patient safety to medicine's most complex supply chain, providing the next-generation technology that advanced therapies need. Today's personalized therapies require new technology strategies.

Vineti combines leading enterprise software expertise with deep, first-hand biopharma experience to develop a cloud-based platform of record that ensures quality, scale, security, efficiency, traceability, and patient safety. The Vineti platform also provides actionable insights to continually optimize the therapy process, accelerating time to revenue and decreasing costs. The PTM® platform supports both autologous and allogeneic therapeutics. Vineti supports a range of small and large pharmaceutical developers, and offers the only independent platform to have been part of successful, expedited cell therapy approvals in the U.S. and EU. Vineti supports hundreds of medical centers worldwide and has been honored as a World Economic Forum Technology Pioneer.

vineti.com

WellSky

WellSky's cell and gene therapy software simplifies supply chain management through a single, comprehensive and flexible platform that centralizes data across entities – seamlessly driving clinical, manufacturing, and operational workflows for autologous and allogeneic therapies. The solution is highly configurable and can quickly adapt to changes in business models and clinical and manufacturing protocols (such as those required with expansion to novel cell and gene therapies). Our innovative technology also delivers an enhanced user experience, increased controls for safety and compliance, systems interoperability, a complete scheduling system, and a robust analytics platform, allowing you to make your data actionable.

wellsky.com

WMDA
matching donors • serving patients

The World Marrow Donor Association (WMDA) consists of organizations and individuals who promote global collaboration and best practices for the benefit of stem cell donors and transplant patients. Together we strive for patients worldwide to have equal access to high-quality cells for transplantation from donors whose rights and safety are protected.

Our aims are: 1) Optimizing 'Search, Match & Connect' 2) Supporting Global Development 3) Promoting Donor Care 4) Ensuring Quality.

wmda.info

AmerisourceBergen
World Courier

World Courier provides specialty logistics services to drive the clinical and commercial success of our partners around the globe. For over 50 years, we've delivered peace of mind through world-class supply chain programs, transport services and storage for time- and temperature-sensitive products, including innovative medicines like cell and gene therapies. Part of the AmerisourceBergen family of companies, we work among 22,000 global team members under one purpose: We are united in our responsibility to create healthier futures. With global certification against three major GDP standards across 140+ offices in 50+ countries, we are driven by a commitment to excellence and to moving health forward, worldwide.

worldcourier.com

Worthington™
Biochemical Corporation

Register to win an iPAD at our booth! New! Animal/Xeno Free Collagenases, DNAses, RNAses and STEMxyme® Collagenase/Neutral Protease Blends. Connect with us for our Catalog, Manuals and NEW Cell Isolation/Tissue Guide and FREE Collagenase Sampling Program. Worthington is an ISO9001 Certified primary supplier of enzymes and biochemicals for primary & stem cell isolation, bioprocessing, biopharm and related applications.

Worthington-Biochem.com

XCELL

Xcell Therapeutics achieved the CellCor™ CD MSC, the world-first Chemically Defined Cell Culture Media for hMSC.

xcell.media

Come celebrate with us...

60 YEARS

ago, in 1961, Drs. James Till and Ernest McCulloch first identified hematopoietic stem cells in mouse bone marrow, in downtown Toronto. This work changed the landscape of scientific discovery in Canada and around the world.

20 YEARS

since the creation of Canada's Stem Cell Network. In that time the Network has built a strong and vibrant community, funding research, training next generation leaders, fostering partnerships and powering Canada's stem cell and regenerative medicine sector.

10 YEARS

of Till & McCulloch Meetings (TMM), Canada's largest gathering for stem cell science. Bringing together Canada's leading stem cell scientists, clinicians, bioengineers and ethicists, as well as industry, government, health and NGO sector representatives from around the world.

YEARS 20 ANS

Join the Stem Cell Network at Virtual TMM2021 – Nov. 15-17

www.tillandmcculloch.ca

See you in
San Francisco!
ISCT
2022
MAY 4-7, 2022
International Society
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