Candidate: Regional Secretary, Europe (2023-2026)

Lindsay Davies, BSc (Hons), PhD, FHEA
Chief Scientific Officer
NextCell Pharma AB
Sweden

Summary of academic and professional background:

My PhD in cell therapy for cartilage repair introduced me to CGT, springboarding me into a career within the field, starting with a postdoc and two fellowship positions in stem/stromal cell biology within the UK. During this time, I discovered a novel stem cell within the oral cavity, which I patented and won multiple awards for. I subsequently moved to Karolinska Institutet, Sweden to learn from world leaders developing stromal cell therapeutics. As an Associate Professor I worked with basic science and clinical trial development using stromal cells. Alongside my academic work, I worked with the Finnish Red Cross Blood Service, Finland and an industrial partner for medical device development. These positions allowed me to experience multiple European countries and working cultures. In 2020, I moved into industry setting up my own consulting company, CellTherEx, to support academics and SMEs spinning out and handling regulatory compliance. Having worked in translational research, I feel strongly about the gap in support, funding and knowledge for academics to realise their ideas. This transition has been very rewarding, with the company growing and offering me the opportunity to join NextCell Pharma, a cell therapy company, developing products for usage in multiple clinical indications. As their Chief Scientific Officer I am proud to have supported their movement from a phase I company, with one initial trial to 4 active Phase I/II trials, international expansion and a phase III in development.

Affiliated professional and commercial associations and any perceived or potential conflict of interests:

- Chief Scientific Officer for NextCell Pharma AB, Sweden
- Chief Executive Officer for CellTherEx Consulting AB, Sweden
- Affiliated Researcher, Department of Microbiology, Tumor and Cell Biology, Karolinska Institutet, Sweden
- Scientific Advisory Board Member for European Tissue Repair Society
- Scientific Advisory Board Member for PL Bioscience GmbH, Germany

None of these roles would offer a conflict of interest with being an officer or director of ISCT.

List of top notable contributions to the field (e.g. publications, patents, reports, products advanced to clinical trial or regulatory approval, asset development, mergers, acquisitions, etc.) from the last 10 years:

Publications
In the period 2012-2022 I have authored 39 publications and gained a H-index of 14.
The most noteworthy publications, showing the breadth of subject matters I have worked with within the realm of cell and gene therapy, its translation and basic biology are listed below with citations (Web of Science as of 2nd January 2023)

Articles
Oral Mucosal Progenitor Cells Are Potently Immunosuppressive in a Dose-Independent Manner Stem Cells and Development 2012 DOI: 10.1089/scd.2011.0434 Citations 35
Do Cryopreserved Mesenchymal Stromal Cells Display Impaired Immunomodulatory and Therapeutic Properties? Stem Cells 2014 DOI: 10.1002/stem.1729 Citations 218
Mesenchymal Stromal Cell Secretion of Programmed Death-1 Ligands Regulates T Cell Mediated Immunosuppression Stem Cells 2017 DOI: 10.1002/stem.2509 Citations 184
Endometrial stromal cells exhibit a distinct phenotypic and immunomodulatory profile Stem Cell Research and Therapy 2020 DOI: 10.1186/s13287-019-1496-2 Citations 19

Reviews
Mesenchymal stromal cells and the innate immune response Immunology Letters 2015 DOI: 10.1016/j.imlet.2015.05.004 Citations 153
MSCs-cells with many sides Cytotherapy 2018 DOI: 10.1016/j.jcyt.2018.01.009 Citations 64

Patents - named inventor
EP 3 816 338 A1 Patent Pending, filed in 2019 "MEDICAL PRODUCT AND METHOD FOR PREPARING THEREOF"
PCT/EP2020/072918 Patent Pending, filed in 2020 "ALLOGENIC COMPOSITION FOR TREATMENT OF CNS DISORDERS"
PCT/GB2009/001443 Patent Granted in 2014 "NOVEL ADULT PROGENITOR CELL"
PCT/EP2021/072621 Patent pending, filed in 2021 "ALLOGENEIC COMPOSITION FOR TREATMENT OF COVID-19"

Clinical trial development
Co-author of clinical trial protocols for:
Treatment of Respiratory Complications Associated With COVID-19 Infection Using Wharton's Jelly (WJ)-Umbilical Cord (UC) Mesenchymal Stromal Cells (ProTrans®): Open Phase IB Clinical Trial (Sweden)
Treatment of Respiratory Complications Associated With COVID-19 Infection Using Wharton's Jelly (WJ)-Umbilical Cord (UC) Mesenchymal Stromal Cells (ProTrans®): a Randomized Phase II Controlled Clinical Trial (Canada)

Products advanced to clinical trials
I have worked as CSO for NextCell Pharma to secure regulatory approval for usage of their mesenchymal stromal cell product, ProTrans for clinical trial usage for the treatment of severe pneumonia associated with COVID-19 infection (Phase I dose escalation in Sweden) and (Phase II double-blind, randomised and placebo-controlled trial in Canada). I have also worked with NextCell Pharma on their paediatric investigation plan for paediatric usage of ProTrans in type I diabetes treatment and their Phase I/II paediatric type I diabetes trial in Sweden. I have also led the discussions with EMA for market authorisation application through their SAWP.

Company formation
In 2020 I transitioned from academia into industry by forming my own advanced therapy consulting company, with the principal mission to address the gap in support and knowledge for

academics and startups/SMEs wishing to spin-out, develop or diversify their portfolio into the area of cell and gene therapy. This has been extremely successful with revenue growing year on year and current investigation into company expansion. Scientific Advisory Work and Mentorship I have been a member of the European Tissue Repair Society scientific advisory board for the last 3 years, with my term ending this year. As a member of this board I have endeavoured to promote the need for scientific collaboration and industrial alliance between the tissue engineering and CGT community, especially with respect to those working in fibroblast and extracellular matrix based approaches collaborating with those in the mesenchymal stromal cell fields. There remains much to be learnt within these areas that is of relevance to all in tumour biology through to tissue repair in sports injuries and CGT for immune related disorders such as Graft versus Host Disease. In addition to this I have been a mentor for the ISCT's ESP programme for the last 2 years, now just entering my third term. I find this programme extremely rewarding for both the mentees and myself as the mentor. I always say to my mentees that I believe I learn as much from them as they can learn from me! It really shows the scope of where young professionals need support and a resource to explore opportunities and which part of the sector they really feel engaged in and wish to pursue.

Scientific Outreach
This aspect of engaging with the wider community and bringing science to the general population has been important to me for many years. Since writing a children's story to explain how the blood system works to children under the age of 5, I have been captivated by the impact of how explaining medicine using concepts that we are all familiar with removes the fear of the unknown and complicated and inspires. Since then, I led scientific outreach programmes in the UK, going into infant and junior schools to promote science and "make science fun". This I continued when I moved to Sweden, working in an International School afterwork programme to teach science to junior school age English speaking children.

Summary of involvement with ISCT in the past five years:

I have been an active member of ISCT for over 10 years. It is important for me to give back for all that I have learnt and enjoyed as a society member. I have been fortunate to have had the opportunity to speak and present posters at many of the meetings, the most recent being the 2021 New Orleans virtual. I am a member of the PDM committee and particulates working group. During 2020-2022 I was a member of the Commercialisation Committee. I have thoroughly enjoyed being an active member of these groups, where I have learnt a great deal on the industrial side of CGT development. It has been a rewarding time, especially as a member of the PDM where I have been fortunate to work with and publish an opinion piece on particulate matter (Cytotherapy 2022 Dec;24(12):1195-1200) and work towards our second piece based on a survey of CGT developers.

I am also a mentor for the ISCT ESP programme, which I have thoroughly enjoyed for the last 2 years and heading into my third term now. This programme I highly recommend to my own team and others I mentor outside of ISCT. It is excellent to have a programme which allows for such open discussion, not tailored to any particular topic. It is really rewarding from my own perspective to see the mentees grow over the year and many of them I have kept in contact with and continue to support when needed even now.

Summary of strategic vision for the Global Society:

I believe that ISCT has positioned itself as a credible society built on strong ethics and a commitment to improve knowledge, regulation, and patient access for CGTs across the globe. I feel honoured to be a part of this movement. As a global society, ISCT has proven its force and has the potential to work with industry partners and regulators alike, to improve and strengthen governance and policy with respect to manufacturing regulations, commercialisation, and reimbursement strategies; with the ultimate aim of CGTs being offered as standard line of care where needed, irrespective of your country of residence.

Due to political and regulatory issues, I believe that Europe still lags behind our North American partners in realising this dream, with issues regarding finances and regulatory hurdles meaning that many global CGT companies are backtracking or cautious about developing their products inside Europe. While understandable, as a European member of the society, I would like to bring this issue to the table and understand exactly the underpinning concerns companies, developers and healthcare providers are experiencing. With this knowledge, I believe that ISCT has the kudos and skill in its society members to address these issues and move policy forward to bring CGT to Europe en force. For me personally, as an academic who transitioned into industry after many years, there are two other issues dear to my heart. I would like to see greater support for academics and startups inside Europe to navigate the valley of death in translating their ideas to a viable clinical product. So many small companies and individual academics hold such innovative ideas that could, given the right support and funding opportunities, lead to new efficacious therapies. I would also like to bring science to the masses and make ISCT a name synonymous with innovative medicine. One of the core limiting factors with CGT development is acceptance. While we may strive to have a medicine that is safe to the authorities and efficacious for use, if the patient doesn't understand or is fearful of such futuristic medicines (in their eyes), then there is no place for commercialisation or widespread usage. We have seen this first hand with the development and "marketing" of mRNA COVID vaccines. The importance of communicating science to the public, our patients, is integral to our own success. I believe that ISCT can play a pivotal role in this fiduciary responsibility and would endeavour to contribute to the implication of such a programme within the global society.