Roadmapping the Clinical and Regulatory Paths of Subcutaneous Products and Technologies

VIRTUAL WORKSHOP

Thursday, February 23, 2023

11:00 AM – 1:00 PM (EST) Part 1: Technologies to Facilitate High-Dose SC Administration

11:00 AM – 11:05 AM
Introduction and Welcome
Ryan Nolan, Ph.D., Halozyme

11:05 AM – 11:30 AM
Subcutaneous Injection Technologies: A Non-Aqueous Approach
Steven Prestrelski, Ph.D., MBA, Xeris Pharmaceuticals

11:30 AM - 12:05 PM
Viscosity Reduction and Stability Enhancement of Monoclonal Antibody Formulations Using Derivatives of Amino Acids
Arvind Srivastava, Ph.D., Avantor Sciences

12:05 PM - 12:40 PM
High Dose Payload Delivery Using Bioerodible Subcutaneous Implants
Stephanie Reed, Ph.D., Secant Group

12:40 PM – 12:55 PM
SC Design Considerations to Minimize Regulatory and Execution Burden for High-Dose SC Biologics
Gautam Shetty, Ph.D., Congruence Medical Solutions

12:55 PM – 1:00 PM
Closing Remarks
Ryan Nolan, Ph.D., Halozyme

3:00 PM – 5:00 PM (EST) Part 2: Trial Designs and Regulatory Considerations for SC Development Paths

3:00 PM – 3:05 PM
Introduction and Welcome
Ryan Nolan, Ph.D., Halozyme

Updated 2/13/2023
3:05 PM – 3:35 PM  **Ultralong Acting Injectables for HIV Treatment and Prevention: Clinical Pharmacology Consideration for Developing the Next Generation of Therapeutics**  Andrew Weber, MS, ViiV Healthcare

3:35 PM – 4:00 PM  **Developing Subcutaneous Dosing Alternatives to High-Dose Intravenous Infusions for Monoclonal Antibodies - Clinical Bridging Approach**  Beate Bittner, Ph.D., F. Hoffmann - La Roche

4:00 PM – 4:55 PM  **Moderated Panel: Trial Designs and Regulatory Considerations for SC Development Paths including Role of Virtual Data in Successful Bridging Studies**  Kaoutar Abbou Oucherif, Ph.D., Eli Lilly  Beate Bittner, Ph.D., F. Hoffmann - La Roche  Ramesh Kashi, Ph.D., Bristol-Myers Squibb  Yow-Ming Wang, Ph.D., US Food and Drug Administration (FDA)  Andrew Weber, MS, ViiV Healthcare

4:55 PM – 5:00 PM  **Closing Remarks**  Ryan Nolan, Ph.D., Halozyme