FDA Workshop: Increasing the Efficiency of Biosimilar Development Programs

September 19, 2022

9:00 am – 4:00 pm Eastern Time

9:00 am – 9:05 am **Welcome**

Christine Corser, PharmD, MS, Analyst, Policy Staff, Office of Therapeutic Biologics and Biosimilars (OTBB)

9:05 am – 9:15 am **Keynote**

Robert Califf, MD, Commissioner, FDA

9:15 am – 9:20 am **Introduction and Overview of the Workshop**

Sarah Yim, MD, Director, OTBB

9:20 am – 10:30 am **Session #1: The Integration of Analytical and Clinical Information to Enhance the Efficiency of Biosimilar Development Programs**

Moderator: Emanuela Lacana, PhD, Deputy Director, OTBB

Speakers/Panelists:

- Peter Stein, MD, Director, Office of New Drugs (OND)
- Steven Kozlowski, MD, Director, Office of Biotechnology Products (OBP)
- Steven Lemery, MD, Director, Division of Oncology III (DO3), OND
- Stacey Ricci, MEng, ScD, Director, Scientific Review Staff (SRS), OTBB
- Joel Welch, PhD, Associate Director of Science and Biosimilar Strategy, OBP

10:30 am – 10:45 am **Break**

10:45 am – 12:15 pm **Session #2: Innovative Statistical Methods for Integration of Data Sources Informing Biosimilar Comparative Clinical Studies**

Moderator: Thomas Gwise, PhD, Director, Division of Biostatistics (DB9), Office of Biostatistics (OB)

Speakers/Panelists:

- Shein-Chung Chow, PhD, Professor of Biostatistics & Bioinformatics, Duke University School of Medicine
- Johanna Mielke, PhD, Data Scientist, Bayer Pharma AG
- Matthew Psioda, PhD, Head of Statistical Innovation, GSK
- Danyu Lin, PhD, Professor, Department of Biostatistics, University of North Carolina
- Peter Thall, PhD, Professor, Department of Biostatistics, The University of Texas MD Anderson Cancer Center

Literature Background for Session #2:

Mielke, J., Schmidli, H., & Jones, B. (2018). Incorporating historical information in biosimilar trials: Challenges and a hybrid Bayesian-frequentist approach. *Biometrical Journal*, *60*(3), 564–582. https://doi.org/10.1002/bimj.201700152

Psioda, M. A., Hu, K., Zhang, Y., Pan, J., & Ibrahim, J. G. (2020). Bayesian design of biosimilars clinical programs involving multiple therapeutic indications. *Biometrics, 76*(2), 630–642. https://doi.org/10.1111/biom.13163

Zeng, D., Pan, J., Hu, K., Chi, E., & Lin, D. Y. (2018). Improving the power to establish clinical similarity in a Phase 3 efficacy trial by incorporating prior evidence of analytical and pharmacokinetic similarity. *Journal of Biopharmaceutical Statistics, 28*(2), 320–332. https://doi.org/10.1080/10543406.2017.1397012

12:15 pm – 1:00 pm **Lunch Break**

1:00 pm – 1:45 pm **Continuation of Session #2**

1:45 pm – 2:00 pm **Break**

2:00 pm – 3:30 pm **Session #3: Biosimilar Comparative Clinical Endpoint Study Design: Choices to Optimize Efficiency**

Moderator: Stella Grosser, PhD, Director, Division of Biostatistics 8 (DB8), OB

Speakers/Panelists:

- Carol Kim, PharmD, Scientific Reviewer, SRS, OTBB
- Kathy Fritsch, PhD, Mathematical Statistician, Division of Biostatistics 3, OB
- Jessica Kim, PhD, Mathematical Statistician Team Leader, DB8, OB
- Wanjie Sun, PhD, Mathematical Statistician Team Leader, DB8, OB
- Yow-Ming Wang, PhD, Associate Director for Biosimilars and Therapeutic Biologics, Office of Clinical Pharmacology
- Steven Lemery, MD, Director, DO3, OND
- Nikolay Nikolov, MD, Director, Division of Rheumatology and Transplant Medicine, OND

3:30 pm – 4:00 pm **Workshop Summary and Concluding Remarks**

Sarah Yim, MD, Director, OTBB