Panel Discussion

Biosimilars: Beginning a Conversation
Pretest Question #1

What are key requirements for a biosimilar to be deemed interchangeable?

A. In any given patient, the biosimilar agent would have the same expected clinical outcome as the reference innovator product JL578

B. The biologic product is highly similar to the reference innovator product based on analytical, animal, and clinical studies JL579

C. Switching innovator and interchangeable products in any given patient more than once is safe and efficacious JL580

D. Both A and C JL581
Pretest Question #2

What types of studies are required by the FDA to determine if there are safety issues with immunogenicity?

A. Analytical studies  JL583
B. Animal studies  JL584
C. Clinical studies  JL585
D. Pharmacokinetic studies  JL586
Panel Members

- Christopher J. Campen, PharmD, BCPS, BCOP (Moderator)
  Clinical Pharmacist
  Greenville Health System

- Kelley D. Mayden, MSN, FNP, AOCNP®
  Nurse Practitioner
  Southwest Virginia Cancer Center

- Ali McBride, PharmD, BCPS, BCOP
  Clinical Coordinator of Hematology/Oncology
  University of Arizona Cancer Center

- Michael Swit, Esq.
  Senior Director, Legal, Regulatory
  Illumina, Inc.
Financial Disclosure

- Dr. Campen has served as a member of the Taiho advisory board.
- Ms. Mayden has nothing to disclose.
- Dr. McBride has nothing to disclose.
- Mr. Swit has nothing to disclose.
Learning Objectives

- Describe the FDA pathway for approval of biosimilars
- Discuss the difference between interchangeable and biosimilar
- Explain immunogenicity and discuss the importance in biosimilar drug development
- Describe the importance of a pharmacovigilance process in biosimilar safety
Posttest Question #1

What are key requirements for a biosimilar to be deemed interchangeable?

A. In any given patient, the biosimilar agent would have the same expected clinical outcome as the reference innovator product JL587
B. The biologic product is highly similar to the reference innovator product based on analytical, animal, and clinical studies JL588
C. Switching innovator and interchangeable products in any given patient more than once is safe and efficacious JL589
D. Both A and C JL590
What types of studies are required by the FDA to determine if there are safety issues with immunogenicity?

A. Analytical studies  JL592
B. Animal studies  JL593
C. Clinical studies  JL594
D. Pharmacokinetic studies  JL595