November 5-8, 2015
JW Marriott Desert Ridge
Phoenix, Arizona

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**

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Posttest Question #2

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**