

Investigator Perspectives on the Development and Use of Oncologic Biosimilars in the Management of Common Cancers

THE CORRECT ANSWER IS INDICATED WITH YELLOW HIGHLIGHTING.

1. Which of the following statements is true regarding biosimilar agents compared to their reference drugs?
  - a. They are similar but not identical
  - b. They have significant differences in efficacy
  - c. They have significant differences in safety
  - d. All of the above
  - e. None of the above
2. The regulatory pathway for the approval of biosimilars includes \_\_\_\_\_.
  - a. Pharmacokinetic and pharmacodynamic studies
  - b. Efficacy studies
  - c. Safety and immunogenicity studies
  - d. All of the above
3. Which of the following statements is true regarding the Phase III HERITAGE trial evaluating a trastuzumab biosimilar versus trastuzumab in combination with docetaxel or paclitaxel for HER2-positive metastatic breast cancer?
  - a. Most patients had prior exposure to trastuzumab for metastatic disease
  - b. All patients had prior exposure to chemotherapy for metastatic disease
  - c. Patients received at least 24 weeks of therapy
  - d. All of the above
  - e. Both b and c
4. If a biosimilar is designated by the FDA as interchangeable, pharmacists may substitute it for the reference drug without notifying the prescribing healthcare provider.
  - a. True
  - b. False
5. For which reference agent is a biosimilar formulation approved for use in the United States?
  - a. Filgrastim
  - b. Bevacizumab
  - c. Trastuzumab
  - d. All of the above
  - e. Both a and b
6. The FDA requires efficacy and safety testing of biosimilars for all indications and does not allow extrapolation from one indication to another.
  - a. True
  - b. False
7. \_\_\_\_\_ is the biosimilar for filgrastim that has received FDA approval for all the same indications as its reference drug.
  - a. Filgrastim-sndz
  - b. Tbo-filgrastim
  - c. Both a and b
8. Which result was demonstrated by the Phase III HERITAGE study evaluating the trastuzumab biosimilar versus trastuzumab in combination with docetaxel or paclitaxel for HER2-positive metastatic breast cancer?
  - a. Similar overall response rates at 24 weeks
  - b. Significant differences in progression-free survival at 24 weeks
  - c. Both a and b
9. Which of the following statements is true regarding biosimilar agents and generic drugs?
  - a. They are manufactured differently
  - b. They must follow different FDA approval pathways
  - c. Biosimilars have the potential to offer greater cost savings
  - d. All of the above
  - e. Both a and b
10. Postmarketing surveillance for adverse events will be important after biosimilars enter clinical practice.
  - a. True
  - b. False