

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

THE CORRECT ANSWER IS INDICATED WITH YELLOW HIGHLIGHTING.

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