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

Video Program

CME Information

TARGET AUDIENCE

This educational activity has been designed to meet the educational needs of medical oncologists, hematologists, hematology-oncology fellows and other allied cancer professionals.

OVERVIEW OF ACTIVITY

The rising cost of healthcare in general and cancer care in particular has prompted growing concern in recent years about the long-term viability of the status quo. One noteworthy advance with the potential to drive down the cost of oncologic care without compromising patient outcomes is the development of biosimilar agents, and it has been projected that the introduction of "biosimilars" will reduce healthcare expenditures by up to $250 billion by 2024.

Importantly, while the market for biosimilars may be in its infancy now, widespread utilization is likely just around the corner, and oncologists must be prepared for this seemingly inevitable paradigm shift. One meaningful way clinicians can move toward this goal is through improved understanding and early adoption of biosimilar products. To facilitate and expedite such understanding and in turn facilitate the provision of high-quality, cost-effective cancer care, this educational activity focuses on the development and regulation of recently approved and investigational biosimilar agents and on available clinical research data.

LEARNING OBJECTIVES

- Evaluate the financial implications for the US healthcare system of the broad adoption of biosimilar agents in the management of various solid and hematologic cancers and related illnesses.
- Compare and contrast the discovery, development and reproduction of generic small-molecule drugs, biosimilars and their respective biologic reference agents, and use this information to counsel patients regarding the safety and efficacy of these therapies.
- Review the regulatory pathways created by the US Food and Drug Administration (FDA) to evaluate and approve biosimilars and reference biologics in order to increase confidence among cancer care professionals regarding the safety and efficacy of these agents.
- Recall available and emerging clinical research data evaluating the relative safety and efficacy of oncology biosimilars, and use this information to support the integration of these agents into the current and future care of patients with cancer.
- Summarize the "interchangeable product" designation assigned by the FDA for specific biosimilars, and explain the expected impact, or lack thereof, of product substitution on patient safety and outcomes.

ACCREDITATION STATEMENT

Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

Research To Practice designates this enduring material for a maximum of 2.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 2.25 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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This CME activity consists of a video component. To receive credit, the participant should review the CME information, watch the video, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and Credit

Form located at **ResearchToPractice.com/Biosimilars19/Video/CME**. The corresponding audio program is available as an alternative at **ResearchToPractice.com/Biosimilars19**.

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Hardware/Software Requirements:
A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 11 or later, Firefox 56 or later, Chrome 61 or later, Safari 11 or later, Opera 48 or later
Adobe Flash Player 27 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: February 2019

Expiration date: February 2020

Select Publications

American Society of Clinical Oncology. **The state of cancer care in America, 2017: A report by the American Society of Clinical Oncology.** *J Oncol Pract* 2017;13(4):e353-e394.

Blackwell K et al. **Pooled analysis of two randomized, double-blind trials comparing proposed biosimilar LA-EP2006 with reference pegfilgrastim in breast cancer.** *Ann Oncol* 2017;28(9):2272-7.

Blackwell K et al. **Comparison of EP2006, a filgrastim biosimilar, to the reference: A phase III, randomized, double-blind clinical study in the prevention of severe neutropenia in patients with breast cancer receiving myelosuppressive chemotherapy.** *Ann Oncol* 2015;26(9):1948-53.

Casak SJ et al. **FDA's approval of the first biosimilar to bevacizumab.** *Clin Cancer Res* 2018;24(18):4365-70.

Cohen H et al. **Awareness, knowledge, and perceptions of biosimilars among specialty physicians.** *Adv Ther* 2017;33(12):2160-72.

Cuello HA et al. **Comparability of antibody-mediated cell killing activity between a proposed biosimilar RTXM83 and the originator rituximab.** *BioDrugs* 2016;30(3):225-31.

Dougherty MK et al. **Perspectives on the current state of the biosimilar regulatory pathway in the United States.** *Clin Pharmacol Ther* 2018;103(1):36-8.

Farhat F et al. **The concept of biosimilars: From characterization to evolution — A narrative review.** *Oncologist* 2018;23(3):346-52.

Franceschetti A, Caldeira R. **Treatment approach for non-Hodgkin lymphoma patients since first biosimilars of rituximab approved in EU5.** *Proc ASCO* 2018;**Abstract 112**.

Frank RG. **Friction in the path to use of biosimilar drugs.** *N Engl J Med* 2018;378(9):791-3.

Hakim A, Ross JS. **Obstacles to the adoption of biosimilars for chronic diseases.** *JAMA* 2017;317(21):2163-4.

Harbeck N et al. **Comparison of efficacy and safety of biosimilar filgrastim in a RCT (PIONEER) and real-world practice (MONITOR-GCSF).** *Proc ASCO* 2018;**Abstract 111**.

Harvey RD. **Science of biosimilars.** *J Oncol Pract* 2017;13(9 Supp):17-23.

Jurczak W et al. **Equivalent efficacy of a biosimilar rituximab and reference rituximab in previously untreated advanced follicular lymphoma: Extended results of ASSIST-FL, a confirmatory phase III study.** *Proc ESMO* 2017;**Abstract 9940**.

Jurczak W et al. **Rituximab biosimilar and reference rituximab in patients with previously untreated advanced follicular lymphoma (ASSIST-FL): Primary results from a confirmatory phase 3, double-blind, randomised, controlled study.** *Lancet Haematol* 2017;4(8):e350-61.

Kim WS et al. **Efficacy, pharmacokinetics, and safety of the biosimilar CT-P10 compared with rituximab in patients with previously untreated advanced-stage follicular lymphoma: A randomised, double-blind, parallel-group, non-inferiority phase 3 trial.** *Lancet Haematol* 2017;4(8):e362-73.

Lyman GH et al. **American Society of Clinical Oncology Statement: Biosimilars in oncology.** *J Clin Oncol* 2018;36(12):1260-5.

Lyman GH et al. **Rationale, opportunities, and reality of biosimilar medications.** *N Engl J Med* 2018;378(21):2036-44.

Lyman GH et al. **In discussion of: Rationale, opportunities, and reality of biosimilar medications.** *N Engl J Med* 2018;379(7):694-5.

Manikhas A et al. **Biosimilar trastuzumab-dkst monotherapy versus trastuzumab monotherapy after combination therapy: Toxicity, efficacy, and immunogenicity from the phase 3 Heritage trial.** *Proc ASCO* 2018;**Abstract 110**.

Markus R et al. **Developing the totality of evidence for biosimilars: Regulatory considerations and building confidence for the healthcare community.** *BioDrugs* 2017;31(3):175-87.

Nabhan C, Feinberg BA. **Behavioral economics and the future of biosimilars.** *J Natl Compr Canc Netw* 2017;15(12):1449-51.

Romera A et al. **Bevacizumab biosimilar BEVZ92 versus reference bevacizumab in combination with FOLFOX or FOLFIRI as first-line treatment for metastatic colorectal cancer: A multicentre, open-label, randomised controlled trial.** *Lancet Gastroenterol Hepatol* 2018;[Epub ahead of print].

Rugo HS et al; Heritage Study Investigators. **Effect of a proposed trastuzumab biosimilar compared with trastuzumab on overall response rate in patients with ERBB2 (HER2)-positive metastatic breast cancer: A randomized clinical trial.** *JAMA* 2017;317(1):37-47.

Select Publications

Rugo HS et al. **A clinician's guide to biosimilars in oncology.** *Cancer Treat Rev* 2016;46:73-9.

Sörgel F et al. **Comparability of biosimilar filgrastim with originator filgrastim: Protein characterization, pharmacodynamics, and pharmacokinetics.** *BioDrugs* 2015;29(2):123-31.

Waller CF et al. **A pharmacokinetics and pharmacodynamics equivalence trial of the proposed pegfilgrastim biosimilar, MYL-1401H, versus reference pegfilgrastim.** *J Cancer Res Clin Oncol* 2018;144(6):1087-95.