StudyCompanion—Narrowing the Gaps: Understanding Biosimilars

A CME Activity

References

1. United States House of Representatives. Washington, DC: United States House of Representatives. *Public Health Service Act.* Section 351 (i)(2). https://legcounsel.house.gov/Comps/PHSA-merged.pdf

2. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

3. Khraishi M, Stead D, Lukas M, Scotte F, Schmid H. Biosimilars: A multidisciplinary perspective. *Clin Ther.* 2016;38(5):1238-1249.

4. Woodcock J, Griffin J, Behrman R, et al. The FDA's assessment of follow-on protein products: a historical perspective. *Nat Rev Drug Discov.* 2007;6(6):437-442.

5. Khraishi M, Stead D, Lukas M, Scotte F, Schmid H. Biosimilars: A multidisciplinary perspective. *Clin Ther.* 2016;38(5):1238-1249.

6. Liu HF, Ma J, Winter C, Bayer R. Recovery and purification process development for monoclonal antibody production. *mAbs.* 2010;2(5):480-499.

7. Müller R, Renner C, Gabay C, Cassata G, Lohri A, Hasler P. The advent of biosimilars: challenges and risks. *Swiss Med Wkly.* 2014;144:w13980.

8. US Food and Drug Administration. Guidance for industry: Q5E Comparability of biotechnological/biological products subject to changes in their manufacturing process. June 2005. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073476.pdf.

9. Li EC, Ramanan S, Green L. Pharmacist substitution of biological products: issues and considerations. *J Manag Care Spec Pharm.* 2015;21(7):532-539.

10. United States House of Representatives. Washington, DC: United States House of Representatives. *Public Health Service Act.* Section 351 (i)(2). https://legcounsel.house.gov/Comps/PHSA-merged.pdf

11. Müller R, Renner C, Gabay C, Cassata G, Lohri A, Hasler P. The advent of biosimilars: challenges and risks. *Swiss Med Wkly.* 2014;144:w13980.

12. Tesser JRP, Furst DE, Jacobs I. Biosimilars and the extrapolation of indications for inflammatory conditions. *Biologics*. 2017;11:5-11

13. United States Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. Silver Spring, MD: US Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER); 2015. Available from: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291128.pdf

14. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

15. Li EC, Ramanan S, Green L. Pharmacist substitution of biological products: issues and considerations. *J Manag Care Spec Pharm.* 2015;21(7):532-539.

16. Khraishi M, Stead D, Lukas M, Scotte F, Schmid H. Biosimilars: A multidisciplinary perspective. *Clin Ther.* 2016;38(5):1238-1249.

17. Arthritis Advisory Committee. *CT-P13 (Infliximab Biosimilar).* https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/arthritisadvisorycommittee/ucm486172.pdf

18. McKeage K. A review of CT-P13: an infliximab biosimilar. *BioDrugs.* 2014;28:313–321.

19. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. *Ann Rheum Dis.* 2013;72(10):1605-1612.

20. Yoo DH, Hrycaj P, Miranda P, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. *Ann Rheum Dis.* 2013;72(10):1613-1620.

21. Khraishi M, Stead D, Lukas M, Scotte F, Schmid H. Biosimilars: A multidisciplinary perspective. *Clin Ther.* 2016;38(5):1238-1249.

22. Li EC, Ramanan S, Green L. Pharmacist substitution of biological products: issues and considerations. *J Manag Care Spec Pharm.* 2015;21(7):532-539.

23. Griffith N, McBride A, Stevenson JG, Green L. Formulary selection criteria for biosimilars: considerations for US health-system pharmacists. *Hosp Pharm.* 2014;49(9):813-825.

24. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

25. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

26. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. *Ann Rheum Dis.* 2013;72(10):1605-1612.

27. Yoo DH, Hrycaj P, Miranda P, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. *Ann Rheum Dis.* 2013;72(10):1613-1620.

28. United States Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. Silver Spring, MD: US Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER); 2015. Available from: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291128.pdf.

29. Infliximab-dyyb prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf

30. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. *Ann Rheum Dis.* 2013;72(10):1605-1612.

31. Yoo DH, Hrycaj P, Miranda P, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. *Ann Rheum Dis.* 2013;72(10):1613-1620.

32. Filgrastin-sndz prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf

33. Etanercept-szzs prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761042lbl.pdf

34. Perez EA, Romond EH, Suman VJ, et al. Trastuzumab plus adjuvant chemotherapy for human epidermal growth factor receptor 2-positive breast cancer: planned joint analysis of overall survival from NSABP B-31 and NCCTG N9831. *J Clin Oncol.* 2014;32(33):3744-3752.

35. Rugo HS, Barve A, Waller CF, et al. 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.

36. Wisman LA, De Cock EP, Reijers JA, et al. A phase I dose-escalation and bioequivalence study of a trastuzumab biosimilar in healthy male volunteers. *Clin Drug Invest.* 2014;34:887–94.

37. Rugo HS, Linton KM, Cervi P, Rosenberg JA, Jacobs I. A clinician's guide to biosimilars in oncology. *Cancer Treat Rev.* 2016;46:73-79.

38. Rugo HS, Linton KM, Cervi P, Rosenberg JA, Jacobs I. A clinician's guide to biosimilars in oncology. *Cancer Treat Rev.* 2016;46:73-79.

39. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

40. Rugo HS, Barve A, Waller CF, et al. 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.

41. Dörner T, Strand V, Cornes P, et al. The changing landscape of biosimilars in rheumatology. *Ann Rheum Dis.* 2016;75(6):974-982.

42. Rugo HS, Linton KM, Cervi P, Rosenberg JA, Jacobs I. A clinician's guide to biosimilars in oncology. *Cancer Treat Rev.* 2016;46:73-79.

43. Müller R, Renner C, Gabay C, Cassata G, Lohri A, Hasler P. The advent of biosimilars: challenges and risks. *Swiss Med Wkly.* 2014;144:w13980.

44. US Food and Drug Administration. Nonproprietary naming of biological products: guidance for industry. August 2015. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm459987.pdf

45. Casadevall N, Edwards IR, Felix T, et al. Pharmacovigilance and biosimilars: considerations, needs and challenges. *Expert Opin Biol Ther.* 2013;13(7):1039-1047.

46. Grampp G, Bonafede M, Felix T, Li E, Malecki M, Sprafka JM. Active and passive surveillance of enoxaparin generics: a case study relevant to biosimilars. *Expert Opin Drug Saf.* 2015;14(3):349-360.

47. US Food and Drug Administration. Nonproprietary naming of biological products: guidance for industry. August 2015. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm459987.pdf

48. Müller R, Renner C, Gabay C, Cassata G, Lohri A, Hasler P. The advent of biosimilars: challenges and risks. *Swiss Med Wkly.* 2014;144:w13980.

49. https://www.fda.gov/downloads/drugsguidancecomplianceregulatoryinformation/guidances/ucm291128.pdf