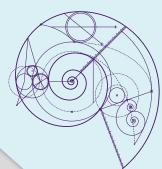
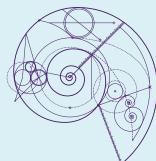
## **Biosimilars:**

Expanding Options for Patient Care

**Extensive use** of and **growing demand** for biologics come at a time when there is **increasing need** for savings and efficiencies for health care systems<sup>1-6</sup>

Biosimilars are **highly similar in terms of safety and effectiveness** to an existing biologic medicine, with no clinically meaningful differences<sup>7</sup>





Biosimilars are **much more complex**than small molecules and are created in living systems that require significant expertise and state-of-the-art technology<sup>8-11</sup>

Biosimilars are evaluated in rigorous analytical, nonclinical, and clinical studies to be licensed by the FDA<sup>7,12</sup>



Analytical



Comparative nonclinical



Comparative clinical pharmacology



Comparative clinical

The need for comparative clinical data will be evaluated on a case-by-case basis depending on residual uncertainty

Biosimilars may offer **additional treatment options** that may increase savings and efficiencies to health care systems and expand the use of biologic therapies, which may lead to better overall health outcomes<sup>13-15</sup>



- Expanded options
- ✓ Increased use of biologics
- ✓ Potential savings

9

Pfizer Biosimilars expands **Pfizer's**commitment to provide therapies
that may improve the lives of
patients, leveraging our global presence
and expertise to deliver high-quality
biosimilars<sup>16-19</sup>

**Biosimilars** 



## References

- 1. Schumock GT, Li EC, Suda KJ, et al. National trends in prescription drug expenditures and projections for 2015. Am J Health Syst Pharm. 2015;72(9):717-736.
- 2. Long D. IMS Health. Perspectives on the evolving biosimilars landscape. Presented at: HDMA Distribution Management Conference and Expo. Orlando, FL; March 8–11, 2015.
- 3. IMS Institute for Healthcare Informatics. Global Outlook for Medicines Through 2018. November 2014. Parsippany, NJ: IMS Health Incorporated; 2014.
- **4.** Centers for Medicare & Medicaid Services. *NHE Projections 2014–2024*. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthAccountsProjected.html. Accessed December 30, 2015.
- **5.** US Food and Drug Administration (FDA). New Molecular Entity and New Therapeutic Biological Product Approvals for 2015. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm430302.htm. Accessed December 30, 2015.
- **6.** Express Scripts. *Specialty Drug Spending to Jump 67% by 2015.* http://lab.express-scripts.com/insights/specialty-medications/specialty-drug-spending-to-jump-67-percent-by-2015. Accessed July 20, 2016.
- 7. US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.* Silver Spring, MD: FDA; 2015.
- 8. Elgert KD. Antibody structure and function. In: Elgert KD, ed. Immunology: Understanding the Immune System. Hoboken, NJ: Wiley & Sons, Inc.; 1998:58-78.
- 9. Kozlowski S, Woodcock J, Midthun K, Sherman RB. Developing the nation's biosimilars program. N Engl J Med. 2011;365(5):385-388.
- 10. Mellstedt H, Niederwieser D, Ludwig H. The challenge of biosimilars. Ann Oncol. 2008;19(3):411-419.
- **11.** US Food and Drug Administration (FDA). *Abbreviated New Drug Application (ANDA): Generics*. July 14, 2015. http://www.fda.gov/Drugs/DevelopmentApprovalProcess /HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/. Accessed January 3, 2016.
- 12. Schneider CK, Vleminckx C, Gravanis I, et al. Setting the stage for biosimilar monoclonal antibodies. *Nat Biotechnol.* 2012;30(12):1179–1185.
- 13. Scheinberg MA, Kay J. The advent of biosimilar therapies in rheumatology—"O brave new world." Nat Rev Rheumatol. 2012;8(7):430-436.
- 14. Henry D, Taylor C. Pharmacoeconomics of cancer therapies: considerations with the introduction of biosimilars. Semin Oncol. 2014;41(suppl 3):S13-S20.
- 15. Strober BE, Armour K, Romiti R, et al. Biopharmaceuticals and biosimilars in psoriasis: what the dermatologist needs to know. J Am Acad Dermatol. 2012;66(2):317-322.
- 16. Data on File. Pfizer Inc, New York, NY.
- 17. Pfizer 2015 Annual Review. *Manufacturing and Supply Chain*. https://www.pfizer.com/files/investors/financial\_reports/annual\_reports/2015/manufacturing-and-supply-chain.htm. Accessed July 20, 2016.
- 18. Hodgson J. WHO guidelines presage US biosimilars legislation? Nat Biotechnol. 2009;27(11):963-965.
- 19. Pfizer Inc. Pfizer Pipeline. February 2, 2016. http://www.pfizer.com/sites/default/files/product-pipeline/Produce\_Pipeline\_Update.pdf. Accessed August 8, 2016.

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