

# **Biosimilars: Myths vs. Facts**

# Myth

Biosimilars are the same as generics.

## Fact

Generics & biosimilars are both alternatives to brand-name reference products. However, the active ingredients of generics are identical to those of to their reference products, while **biosimilars are highly similar** to theirs.<sup>1</sup> Because biosimilars are not identical to their reference products, they go through a different process for approval.<sup>2</sup>

Biosimilars are alternatives to their reference biologic products and they are produced from living organisms and are generally large and complex molecules.<sup>1</sup>



# **Myth**

Biosimilars aren't as safe or effective as reference products.

### Fact

#### Biosimilars **undergo testing** to demonstrate:<sup>3</sup>

- compared to the reference product
- the originator biologic product

Biosimilars are monitored as part of post-market surveillance to evaluate safety.<sup>3</sup>



# Myth

Biosimilars cannot impact health care system costs.

### Fact

Biosimilars create competitive pricing for biologics, helping to potentially:<sup>4</sup>

- **Reduce** health care system costs
- Increase access to biologic medicines



Biosimilars add to the high costs already burdening the health care system.

# Fact

Since the FDA passed the Biologics Price Competition and Innovation Act, biosimilars saved the US health care system over \$37 billion and have the potential to save an estimated \$104 billion from 2020-2024.5



© 2021 Organon group of companies. All rights reserved. HQ-NON-110077 05/21

References: 1. US Food and Drug Administration. Biological product definitions. Accessed May 10, 2021. https://www.fda.gov/files/drugs/published/Biolog uct-Definitions.pdf 2. Scientific considerations in demonstrating biosimilarity to a reference product. FDA Web site. Accessed May 10, 2021. www.fda.gov/downoads/drugs/guidances/ucm291128.pdf 3. US Food and Drug Administration. What is a Biosimilar? Accessed May 10, 2021. https://www.fda.gov/media/108905 4. US Food and Drug Administration. Biosimilars action plan: balancing innovation and competition. July 2018. Accessed April 28, 2021. https://www.fda.gov/media/114574/download 5. Aitken M, Kleinrock M, Muñoz E. Biosimilars in the United States 2020–2024: competition, savings, and sustainability. IQVIA Institute for Human Data Science report. September 29, 2020. Accessed April 28, 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-inthe-united-states-2020-2024

• No clinical meaningful differences in **safety**, **purity and potency** 

• That it's designed to **work in the body in the same** way as