Biosimilars 101

Biosimilars deliver comparable clinical utility, safety and quality as reference products, allowing expanded patient access.

What Are Biosimilars?

Biosimilars are safe and effective therapeutics for some of the most common yet difficult to treat diseases that offer expanded patient access and cost savings, allowing resources in the healthcare system to address more innovative therapies.

Biosimilars are based on biologic drugs, which are drugs produced from a living organism, rather than made from synthetic chemicals such as pills. Like biologics, biosimilars treat some of the most common but complex and life-threatening diseases today – conditions like diabetes, arthritis, and cancer.

Biosimilars deliver comparable clinical, safety and quality results as the reference product, but at a significant cost savings.

Why Are They Important?

Biosimilars have historically cost at least 20-30 percent less than the reference product, which can cost over $100,000 per year. These cost savings from biologics allows patients expanded access to these complex drugs globally. By improving access to biologics through biosimilars, we can ensure all patients have the potential to receive life-changing treatments.

The reduced cost of biosimilars will also lead to significant cost savings in the wider healthcare market. For example, savings generated by biosimilars from 2007 through 2020 are expected to reach as much as €33 billion in eight EU countries alone. Based on estimates drawn from other markets, the introduction of biosimilars could save the American healthcare system up to $250 billion by 2024, and the U.S. federal government more than $12 billion in the first ten years. These savings create resources to enable access to other innovative treatments, improving the lives of all patients.

Overall, biosimilars foster competition in the market, which will not only lead to savings for the healthcare system and consumers, but also will provide expanded patient access to life-saving biologic medicines and continued therapeutic innovation.

Are They Safe?

For years, biosimilars have been safely used by patients in Europe, Australia and other countries. In the U.S., biosimilars are only approved by the Food and Drug Administration (FDA) when they are proven to have no clinically meaningful differences in terms of safety, purity and potency when compared to the reference product. This means that biosimilars are expected to provide the same clinical benefits as the reference product at the same level of safety that's continually tested and regulated by the FDA.

Are They Effective?

Biosimilars must undergo rigorous testing and are only approved when they are proven to deliver the same benefits to patients as their reference product. In addition, Pfenex's robust bioanalytical approach to the development of biosimilars ensures our products have the potential to achieve a fingerprint-like identity to the reference product – making them highly comparable to the reference product.

* Cautionary note regarding forward-looking statements can be found on the reverse side

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on our management's beliefs and assumptions and on information currently available to management. These forward-looking statements include, among others, statements regarding safety and effectiveness of biosimilars, projected biosimilar regulatory pathways and clinical trial requirements, growth opportunities in the emerging biosimilar market, future cost savings, and potential to expand patient access. Forward-looking statements are typically identified by words like "believe," "anticipate," "could," "should," "estimate," "expect," "intend," "plan," "project," "will," "forecast," "budget," "pro forma," and similar terms. Factors that could cause Pfenex's results to differ materially from those expressed in forward looking statements include, without limitation, uncertainties inherent in the clinical drug development process, including lengthy, time consuming and inherently unpredictable regulatory reviews and delays in clinical trials; products and product candidates may cause serious adverse side effects or have properties that delay or prevent regulatory approval or limit their commercial profile; if approved, risks associated with market acceptance, including pricing and reimbursement. Forward-looking statements represent our management's beliefs and assumptions only as of June 10, 2015. You should read our Annual Report on Form 10-K for the year ended December 31, 2014 and our subsequent reports filed with the SEC, including the Risk Factors set forth therein, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.