LESSONS LEARNED FROM EUROPEAN BIOSIMILAR EXPERIENCE

Using Real-World Biosimilar Experience as Performance Data

Data on biosimilars in the real-world setting are increasing as clinical experience with biosimilars to treat autoimmune conditions such as inflammatory bowel disease, psoriasis, and rheumatoid arthritis grows.

Publishing postmarketing surveillance and other observational studies of **real-world evidence (RWE) offers an important opportunity for manufacturers to provide payers with potential cost-savings data** in addition to sharing additional effectiveness and safety evidence with physicians.[1] Uptake trends of biosimilars in other markets can help inform adoption strategies in the United States.

A Closer Look at EU Share Data for Adalimumab Biosimilars

With a longer-standing biosimilar marketplace, Europe has a wealth of real-world evidence on biosimilars.[2, 3]

Data reveals that uptake of adalimumab biosimilars has been strong:

Within a year and a half of the first adalimumab biosimilars entering EU markets, the availability of adalimumab biosimilars in Europe resulted in **HUMIRA®'s manufacturer reporting a**

31.1%

decrease in net revenue in 2019.[4]

Uptake of biosimilars to HUMIRA in the EU continues to increase, and **biosimilar products now make up nearly**

66%

of the adalimumab share.[5, 6]

Adoption of adalimumab biosimilars is higher in some EU countries due to varying healthcare systems and government policies.

For example, the **AMGEVITA®*** share differs by country, with:

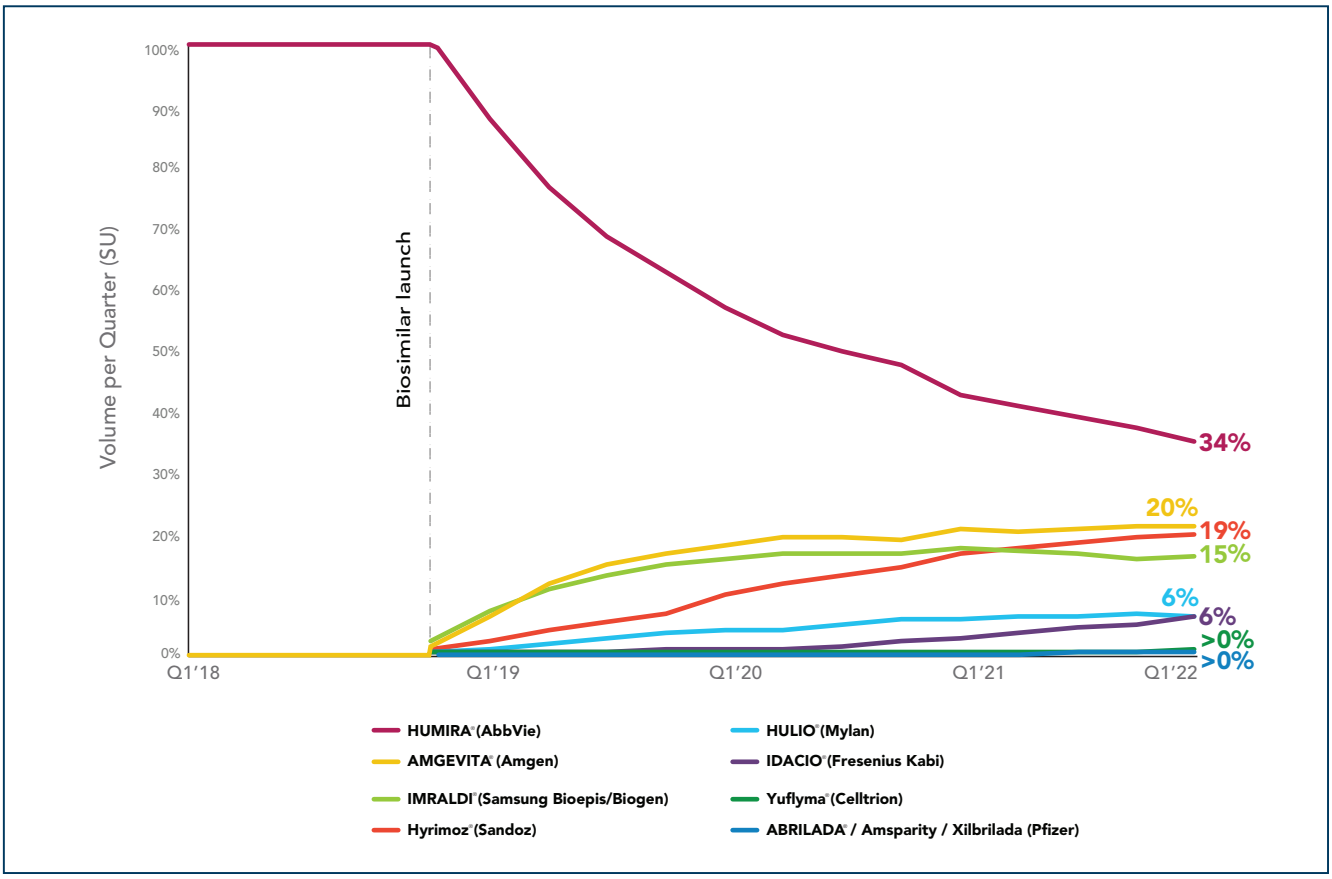
41% share in the UK

20% share in Germany

19% share in France

*This is for informational purposes only. AMGEVITA® has launched in Europe. AMJEVITA™ is currently not available commercially and will not be commercially available in the United States until on or after January 31, 2023.

Figure 1: Adalimumab Volume Analysis in the EU[5, 6]



While the planned launches of biosimilars to HUMIRA® beginning in 2023 could be a pivotal moment for the US marketplace, it is important to note when making comparisons that fundamental differences in the US and EU marketplaces could impact biosimilar uptake. These differences include varying reimbursement policies and regulations.

Connecting the Dots

Between 2017-2021, spending on new and existing autoimmune products exceeded any other therapeutic area, reaching $42 billion.[7] Biosimilars have the potential to offer more economical options for payers and health systems to help manage costs.

Increasing data from the real-world will continue to help US payers and health systems learn from global biosimilars experiences and expand the variety of clinical, economic, and performance data available to help them make informed coverage decisions.

For more information on the future state of the marketplace for biosimilars, you can view Amgen's 2022 Biosimilar Trends Report here:

www.AmgenBiosimilars.com

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3 Barbier L, Ebbers HC, Declerck P, Simeons S, Vulto AG, Huys I. The efficacy, safety, and immunogenicity of switching between reference biopharmaceuticals and biosimilars: a systematic review. Clin Pharmacol Ther. 2020;108(4):734-755.
4 Coghlan J, Hongliang H, Schwendeman AS. Overview of Humira biosimilars: current European landscape and future implications. J Pharm Sci. 2021;110(4):1572-1582.
5 Data on file, Amgen; [1]; 2022.
6 Data on file, Amgen; [2]; 2022.
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