TRIANGLE INSIGHTS GROUP by Valerís

Biosimilars Commercialization: Lessons Learned from Adalimumab and Four Necessary Approaches

Authors:
Matthew Haynes, Ph.D.
Ryan Coe, Ph.D.

July 2024

WHITE PAPER

Introduction

As manufacturers seek to capitalize on blockbuster biologic LOEs in the coming years, the adalimumab market has proven that a successful biosimilar launch is not guaranteed. Despite early access being achieved by leading competitors, Humira's position in the market and likely portfolio-level rebating were able to block nearly all traditional approaches to volume conversion since biosimilars began entering the market ~18 months ago. These events are leading biotech executives to grapple with questions they may not have considered previously:

- *Will I have to contract at the portfolio level or as a private-label partnership to incentivize volume conversion with payers?*
- *Is my organization willing/able to "wait out" the competition following initial price erosion(s)?*
- *Will the present value of the long-term margin be enough to justify the up-front investment in biosimilar development?*

Given these dynamics, several manufacturers are already beginning to pivot their strategy away from biosimilars (e.g., Coherus BioSciences divested Yusimry (Humira biosimilar))[1].

Through our Biosimilar Center of Excellence, Valeris acts as a strategic and implementation partner to address the recurring challenges of the biosimilar market. To highlight a subset of those capabilities, we outline four "lessons learned" from the adalimumab biosimilars market and how Valeris and its subsidiaries' unique blend of offerings (e.g., Patient Support Services, Data & Insights via Policy Reporter by Valeris, and inclusive of Commercial Strategy via Triangle Insights Group by Valeris) can support manufacturers in developing a holistic approach to biosimilar commercialization.

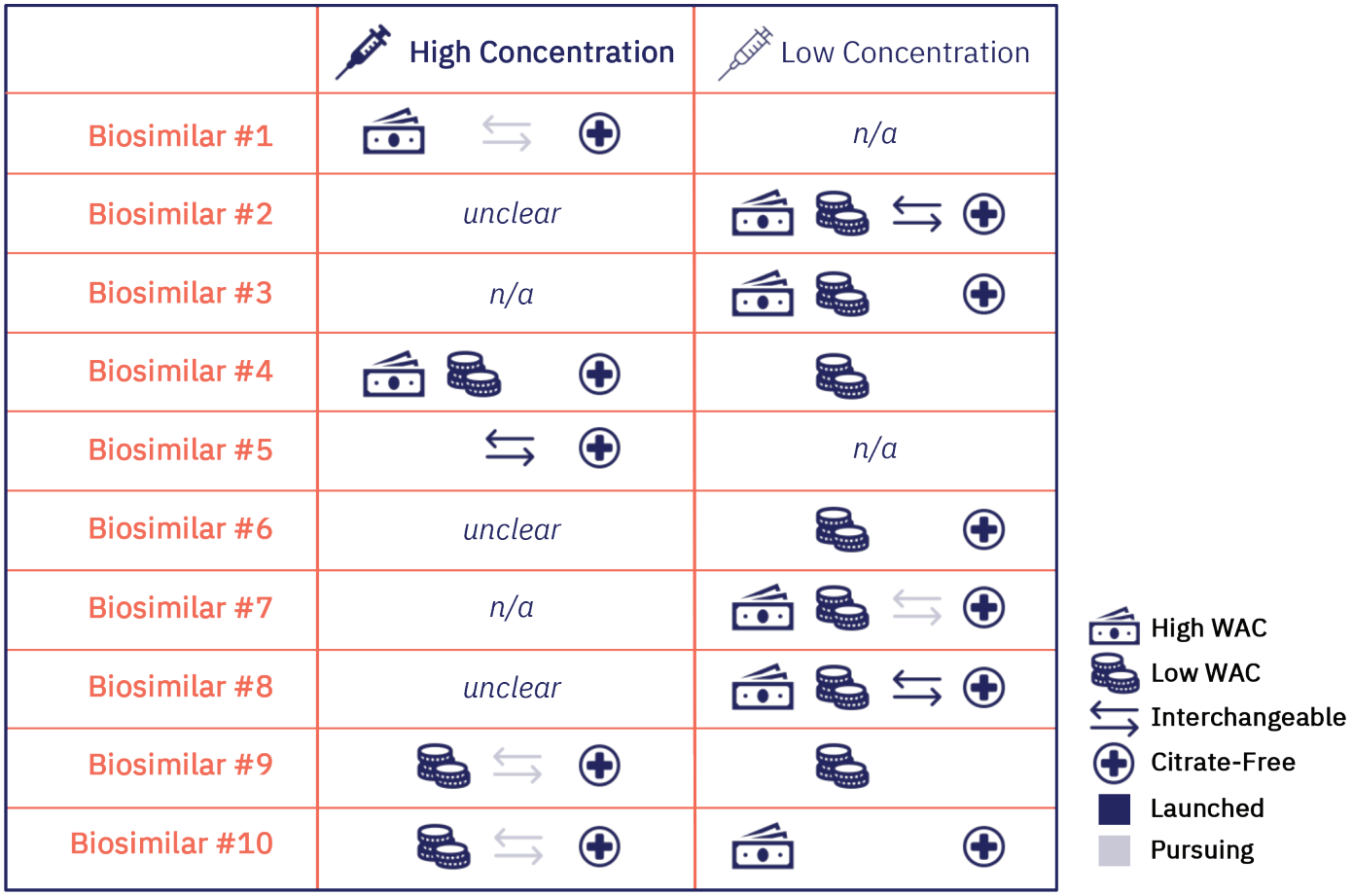
Lessons Learned from Adalimumab: Four Necessary Approaches for Biosimilars Manufacturers

Lesson #1: Predict Market Erosion Based on Competition and Biosimilar Value Proposition (Perspectives from Triangle Insights Group by Valeris)

As manufacturers progress through product development, leadership should scenario plan around the impact of manufacturer capabilities/portfolio and product attributes on expected price and volume erosion. While the slow volume erosion for Humira to date has been notable, it is not unprecedented (e.g., Remicade and Lantus biosimilar launches), nor is it guaranteed to follow every biosimilar launch in the future. Importantly, biosimilar markets have experienced a broad spectrum of price and volume erosion trajectories.[2]

However, likely portfolio-level rebates have been difficult for payers to relinquish thus far, with most payers outside of CVS having been unwilling to 'pick a winner' to date (traditional biosimilar launches comprise ~6% of total adalimumab volume share, and even private label biosimilar volume has stabilized at 14% volume share through June 2024[5]). Since early entrants did not, at the time, provide the full suite of competitive product attributes (citrate-free, high/low-concentration, interchangeability, high/low WAC options; Figure 1), payers likely saw a greater risk in premature volume conversion relative to increased portfolio-level rebates from the parent brand. In addition, as no biosimilar manufacturer through 2023 had launched a high-concentration formulation with interchangeability – a designation that FDA has begun to ease the process for manufacturers to demonstrate sufficient evidence[6] – payers were initially limited in their ability to actively manage biosimilar utilization. These kinds of scenario-minded and value proposition-oriented perspectives have been repeatedly implemented into engagements by Valeris's consultancy services via Triangle Insights Group, to help their clients properly anticipate and prepare for the markets in which their biosimilars will enter.

Figure 1: Snapshot of the adalimumab biosimilar United States market: Top-10 entrants (Q1 2024 update).



Lesson #2: Highlight Key Segments to 'Win' Preferential Access and Drive Volume Conversion (Perspectives from Policy Reporter by Valeris)

While value proposition development and thorough scenario planning remain essential to prepare for biosimilar market entry, volume still needs to be converted following launch. With portfolio contracting and the emergence of multiple private-label partnerships,[3] it is becoming even more important to demonstrate initial market access and share as a proof point for future contracting with larger payers. These proof points typically require a deeply segmented understanding of the market access landscape and an ability to reach and incentivize stakeholders (e.g., regional payers, health systems) whose perspectives on value proposition may differ significantly from the larger payers. These kinds of data-driven segmentation approaches (e.g., low-control vs. high-control payers, clinical vs. UM restrictions) are a key solution of Policy Reporter as they support clients in payer targeting activities and help clients tailor their access strategies to convert volume.

Lesson #3: Carefully Consider Pricing and Margins Relative to Necessary and Sufficient Patient Support Services (Perspectives from Valeris Patient Support Services)

Historically, biosimilar manufacturers have relied on benchmarking to identify the level of patient support services needed to remain competitive to the parent brand. However, this was often enabled by slower erosion of prices over time, producing margins that permitted those relatively robust patient services. The rapid price erosion observed in the US adalimumab market (e.g., multiple biosimilars are priced at 80%-85% off Humira WAC[4]) has transformed those expectations. Today, manufacturers must prepare for a broad spectrum of potential pricing, access, and volume conversion outcomes – outcomes that will define the financial resources available to provide patient support services. Manufacturers are increasingly recognizing the need for not just a single in-house patient support services approach, but a suite of potential strategies and offerings customized by payer type that can be tailored to the manufacturer's needs and rapidly deployed as the market access landscape evolves. This kind of dynamism is recognized as a core market need by Valeris Patient Support Services, which supports its clients in developing bespoke approaches to fulfillment pull-through that can meet biosimilar manufacturers' requirements in an increasingly complex landscape.

Lesson #4: Identify Key Leakage Points for Patients and Track Leakage Following Biosimilar Launch (Holistic Perspectives Across Triangle Insights, Policy Reporter, and Valeris Patient Support Services)

Even with an optimized strategic approach (e.g., differentiated value proposition, a robust market access strategy, and a flexible approach to patient support services), manufacturers may still find themselves in a position where they aren't generating expected volume. In these circumstances, Valeris often finds manufacturers shuffling accountability around their different business units. For example, Market Access may hold Patient Support Services responsible for lower pull-through, Patient Support Services may criticize Market Access for lower volume generation, and both may hold Commercial Strategy culpable for value themes and messaging that aren't resonating. Without an integrated approach to strategy development and implementation, it can be challenging to identify the true barriers to volume conversion. By pairing a claims-based approach to market access and prescription fulfillment tracking with strategic insights generation across patient and prescription journeys, Valeris blends patient support services, access data and insights, and commercial strategy to support biosimilar manufacturers in driving volume and preventing leakage (Figure 2).

Figure 2: Valeris's integrated approach to biosimilar strategy development and implementation.

- Value Proposition Development
- Go-to-Market Strategy Development
- Gross-to-Net Pricing Optimization
- Commercial Launch Scenario Planning
- PIE Strategy and Message Testing

- Competitive Payer Landscape Analysis Account Segmentation and Targeting
- Restriction Benchmarking and Scoring
- Time-to-Policy Coverage Analysis
- Policy and Formulary Dashboards

- Patient Access/Affordability Solutions
- Non-Commercial Dispensing Pharmacy
- Valeris eServices Curator
- Nursing Support Services
- Patient Engagement and Adherence
- Clinical Trial Support

Though manufacturers have begun to see a shift in volume as the adalimumab biosimilar market continues to evolve (e.g., as CVS Caremark removed brand Humira off many formularies starting in April[3,5]), the dynamics that led to slow erosion should not be forgotten. The lessons outlined above, among others, should be foundational to any biosimilar manufacturer's launch strategy moving forward. Contact Valeris today to learn more about how we can help you navigate complexity and accelerate value.

References

1 Pharmaceutical Technology. "Coherus offloads Humira biosimilar Yusimry for $40m." Published June 2024.

2 Amgen. "2022 Biosimilar Trends Report"; Cardinal Health. "2023 Biosimilars Report: Tracking market expansion and sustainability amidst a shifting industry"; Samsung Bioepis. "Biosimilar Market Report: 4th Edition, Q1 2024". Accessed March 2024.

3 Fierce Pharma. "CVS Caremark to kick AbbVie's Humira off some formularies in favor of cheaper biosimilars". Accessed March 2024; Boehringer Ingelheim. "Boehringer Ingelheim expands access to adalimumab-adbm injection, the company's biosimilar to Humira®." Published May 13, 2024.

4 RedBook. Accessed March 2024.

5 Deutsche Bank report, published June 28th, 2024

6 Endpoints News. "FDA makes it easier for biosimilars to obtain interchangeability designations." Published June 20, 2024

About Valeris

Valeris is the leading integrated commercialization partner for life sciences companies.

We deliver partners end-to-end commercial solutions that work together flexibly to provide data and insights, patient support services, and healthcare provider engagement.

Backed by proven industry expertise and results-driven technology, Valeris helps navigate the complex life sciences marketplace to accelerate value, enhancing business results and patient lives alike.

For more information about Valeris, please visit **Valeris.com**.