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First Interchangeable Humira Biosimilar Approved In US

Boehringer Ingelheim's Cyltezo Adalimumab Rival Is Granted Second Ever FDA Designation

by David Wallace

Boehringer Ingelheim has won a landmark first US interchangeability designation for a biosimilar to Humira, with the firm's Cyltezo version of adalimumab representing the second ever interchangeable biosimilar approved by the FDA.

Boehringer Ingelheim's Cyltezo (adalimumab-adbm) has been approved as the first US interchangeable biosimilar to Humira, and only the second interchangeable biosimilar overall, by the US Food and Drug Administration.

The biosimilar – which was initially approved by the FDA in August 2017 – is currently scheduled to be among a chasing pack of Humira biosimilars that are expected to hit the US market in 2023, after Amgen launches its Amjevita (adalimumab-atto) version at the beginning of the year, under a series of settlement deals between biosimilar sponsors and originator AbbVie. (Also see "*Biosimilar Humira Settlements Stand Firm In US*" - Generics Bulletin, 10 Jun, 2020.)

Boehringer Ingelheim has an expected launch date of 1 July 2023, putting it just after Samsung Bioepis on 30 June. (Also see "*Boehringer Settlement Jumps The Queue For Biosimilar Adalimumab*" - Generics Bulletin, 15 May, 2019.)

Boehringer Makes Case For Interchangeable Adalimumab Biosimilar

By Dean Rudge

26 Apr 2021

Announcing the FDA's approval of its supplemental biologics license application, Boehringer Ingelheim said that the

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interchangeability application was "supported by positive data from Boehringer Ingelheim's Phase III randomized VOLTAIRE-X clinical trial," results of which were reported earlier this year (*see sidebar*).

The company said the agency action "marks the first FDA approval for such a study," with data showing that "switching several times between Cyltezo and Humira resulted in no meaningful clinical differences for pharmacokinetics, efficacy, immunogenicity, and safety."

> Boehringer Ingelheim, which is looking to be among the limited players to offer an interchangeable biosimilar in the US, has reported positive switching data from the company's "first-of-its-kind" Phase IIIb Voltaire-X study.
>
> *Read the full article here*

Moreover, the company emphasized, the FDA interchangeability designation means that the biosimilar is deemed interchangeable – and thus eligible for pharmacy-level substitution – across all approved indications.

"We are proud to be the company driving the advancement of biosimilars and delivering the first and only interchangeable biosimilar with Humira," commented Thomas Seck, senior vice president of medicine and regulatory affairs at Boehringer Ingelheim. "It is a true milestone and an important step forward for broader adoption in the US and for patient access to affordable medicines."

He insisted that "the interchangeability status of Cyltezo reinforces our goal of expanding overall treatment options and contributing to the quality and sustainability of the US healthcare system." However, aside from Cyltezo in the US, the company said in 2019 that it had otherwise abandoned biosimilars. (Also see "*Why BI Bid Farewell To Biosimilars* " - Scrip, 8 May, 2019.)

The interchangeability designation for Cyltezo comes after Viatris earlier this year won the first ever interchangeability designation from the FDA for its Semglee (insulin glargine-yfgn) biosimilar to Sanofi's Lantus. (Also see "*Viatris Wins Landmark First US Interchangeability Designation For Semglee*" - Generics Bulletin, 29 Jul, 2021.)

But Boehringer Ingelheim's approval could be of additional interest for industry stakeholders as it offers the first published data on what a successful switch study looks like. (Also see "*Boehringer Ingelheim Wins Interchangeable Biosimilar To Humira, Setting Benchmark For Switching Studies*" - Pink Sheet, 17 Oct, 2021.)

Sponsors Divided Over Need For Interchangeability

Biosimilars applicants are split on the need for an interchangeability designation to successfully

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compete against Humira and other adalimumab biosimilars, as well as on the need for a separate interchangeability standard more broadly.

Like Boehringer, Coherus Biosciences plans to launch its own Humira biosimilar on 1 July 2023, but unlike its rival Coherus is not pursuing interchangeability.

"I think it's important to keep in mind that interchangeability thus far has not been a requirement at all to support biosimilar adoption," Coherus chairman, president and CEO Denny Lanfear observed earlier this year. "What we'd say is that our payer research indicates that interchangeability will not be a major impediment to biosimilar adoption specifically in the Humira market." Coherus, he said, expected the payer to be "very, very active in that market, but we don't expect any requirement to be interchangeable or not." (Also see "*Coherus Distances Itself From Biosimilar Interchangeability*" - Generics Bulletin, 7 May, 2021.)

Meanwhile, Samsung Bioepis has suggested that the existence of a separate interchangeability standard "may cause misunderstanding and misinterpretation of the scientific rigor that goes into biosimilar development [and] approvals," insisting that an interchangeability designation is not necessary to drive uptake in the US. (Also see "*Samsung Bioepis Raises Fresh Questions For Biosimilar Interchangeability*" - Generics Bulletin, 14 May, 2021.)

Biosimilar Interchangeability: A Blessing Or A Curse?

By David Wallace

09 Jul 2021
Biosimilar interchangeability is a hot topic in the US, with the first FDA decision on a formal interchangeability designation expected this month. But across the industry, views differ dramatically on the desirability and likely impact of this additional standard to biosimilarity.

Read the full article here

However, Alvotech is pursuing an interchangeability designation for its AVT02 proposed adalimumab biosimilar, which recently saw FDA action delayed due to pandemic-related obstacles to the agency conducting the necessary inspections. (Also see "*Alvotech Suffers Delay On Higher-Strength Adalimumab In US*" - Generics Bulletin, 21 Sep, 2021.)

The firm recently announced positive data from a switching study (Also see "*Alvotech Champions Switching Data As Clock Ticks On Adalimumab Filing*" - Generics Bulletin, 10 Sep, 2021.) and is also one of the few adalimumab biosimilar filers to have not settled with AbbVie, remaining embroiled in litigation that is due to be decided by October 2022. (Also see "*Alvotech Sees AbbVie's Humira Trade Secrets Case Thrown Out In US*" - Generics Bulletin, 11 Oct, 2021.)

Pfizer has also been named as among those firms pursuing an interchangeability designation as part of efforts to compete with Humira, for the firm's Abrilada (adalimumab-afzb) approved

biosimilar, which is set to launch on 20 November 2023 (Also see "*Pfizer's FDA-Approved Adalimumab Faces Four-Year Wait*" - Generics Bulletin, 18 Nov, 2019.)

AbbVie had in 2020 forecasted that two Humira biosimilars entering the market in 2023 would hold interchangeability designations. (Also see "*AbbVie Assumes Two Interchangeable Humira Biosimilars In 2023*" - Generics Bulletin, 3 Dec, 2020.)

It remains to be seen how the year of exclusivity that accompanies first interchangeability designations – and is expected for Boehringer Ingelheim's biosimilar – will affect competition in the adalimumab market, especially given that Alvotech is pursuing a different, higher-concentration formulation.