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Fresh Wave Of Adalimumab Biosimilars Hits US

Multiple Humira Biosimilar Sponsors Confirm Launch, Offering Details Including Pricing

by **David Wallace**

As launch dates arrive under settlement agreements with Humira originator AbbVie, multiple firms have introduced adalimumab biosimilars in the US, confirming launch and pricing details – with one biosimilar following in the footsteps of Coherus by announcing an 85% discount to the originator.

Multi-source US biosimilar competition to Humira (adalimumab) is finally a reality, with multiple sponsors confirming launches of and pricing details for their rivals to the top-selling immunology brand.

After Amgen launched its Amjevita (adalimumab-atto) version at the end of January this year, the market has been preparing for as many as eight further versions to launch around the start of July, under a series of settlements with originator AbbVie.

Generics Bulletin recently took a detailed look at the various competing biosimilars set to launch over the coming days (see *sidebar*).

Two firms that recently scooped covered preferred listings on the formulary of pharmacy benefit manager Optum Rx – Sandoz and Boehringer Ingelheim – announced their biosimilar launches on 1 July. (Also see "[Sandoz, Boehringer's](#)

Generics Bulletin Explains: The Next Wave Of US Humira Biosimilars

By **David Wallace**

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Following Amgen's debut of the first US Humira rival earlier this year, as many as eight

[Interchangeable US Humira Biosimilars Land Preferred Status](#)" - Generics Bulletin, 26 Jun, 2023.)

Boehringer Ingelheim highlighted that its Cyltezo (adalimumab-adbm) version, available as a pre-filled syringe or as a pen auto-injector, was the “first and only US Food and Drug Administration-approved interchangeable biosimilar to Humira.”

further FDA-approved adalimumab biosimilars are about to launch. *Generics Bulletin* breaks down all the different players and how they are positioning themselves in such a competitive market.

[Read the full article here](#)

The company’s biosimilar commercial lead, Stephen Pagnotta, said the product “reinforces our ultimate goal of providing a more affordable and accessible treatment option for this community, and we look forward to seeing the impact it will have across the US.”

The FDA’s interchangeability designation allows pharmacists to substitute a biosimilar for its reference biologic without consulting the original prescriber, subject to state law (Also see "[Cutting Through The Confusion On US Biosimilar Interchangeability](#)" - Generics Bulletin, 5 Aug, 2022.) – and adalimumab’s presence in the retail channel makes this aspect particularly pertinent.

Meanwhile, Sandoz said the launch of its Hyrimoz (adalimumab-adaz) high-concentration 100mg/ml version would be supported by “Sandoz One Source for Hyrimoz, a robust patient support program that provides educational, reimbursement and affordability support.”

“This is an important moment for Sandoz and for the millions of patients living with chronic inflammatory diseases in the US,” said Sandoz’s president for North America, Keren Haruvi. “With this launch, we are entering the US immunology market and continuing to fulfill our commitment to expand access to important medicines for patients.”

“Sandoz has a long history of developing and marketing biosimilars that generate healthcare savings and enhance competition that drives innovation in the market,” Haruvi stated. “We are pleased to continue this legacy in the US with Hyrimoz, which offers another treatment option for those who need adalimumab but might have previously been unable to access or afford this critical medicine.”

Samsung Bioepis And Organon Opt For 85% Discount

Samsung Bioepis and partner Organon also confirmed their biosimilar launch at the start of July, revealing that their Hadlima (adalimumab-bwwd) version – which, like Sandoz’s Hyrimoz, is approved in both high-concentration and low-concentration formulations – would be available at a significant discount to the originator.

A carton including two pre-filled pens or two pre-filled syringes of Hadlima “is available at a list price (wholesale acquisition cost) of \$1,038,” the partners announced, “which represents an 85% discount in comparison to the list price of Humira, in order to enable expanded access to patients.”

“As the largest loss-of-exclusivity event in pharmaceutical history, this is a singular moment for the US health care system to embrace biosimilars,” said Organon CEO Kevin Ali. “Every stakeholder should be invested in the success of this market to realize the value biosimilars can create for patients, providers, and the US health care economy.”

Ali said the firm was “thrilled to now provide Hadlima in the US at a more affordable cost and expand much-needed access to adalimumab. With our deep biosimilar commercial experience, a new comprehensive patient support program, and our dedication to providing exceptional HCP support, we are immediately well-positioned to make a positive impact.”

At the same time, Samsung Bioepis president and CEO Christopher Hansung Ko said the Hadlima launch “marks an important milestone towards expanding treatment options for millions of patients suffering from chronic autoimmune diseases in the US,” insisting that “based on our robust track record over the past four years with approximately 6.8 million units of our adalimumab biosimilar supplied in ex-US markets, we are well-positioned to deliver this life-changing medicine to patients through stringent quality control, rigorous manufacturing, and supply resilience.”

Coherus had recently announced that its Yusimry (adalimumab-aqvh) biosimilar would be priced at an 85% discount to Humira, or even cheaper through Mark Cuban’s Cost Plus Drugs company (see sidebar).

However, this move led to legal wrangling with AbbVie over claims that it violated the pair’s settlement agreement. (Also see “[Coherus And AbbVie Trade Legal Blows Amid Radical Adalimumab Price Offering](#)” - Generics Bulletin, 15 Jun, 2023.)

Another biosimilar sponsor to have confirmed launch is Celltrion, which is marketing the third and so far final high-concentration adalimumab biosimilar to

Coherus Plots ‘Lowest Price Adalimumab’ With Huge Discount, Ties Up With Mark Cuban

By [Dean Rudge](#)

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Coherus BioSciences had teased a “compelling value proposition” for its Yusimry (adalimumab-aqvh) biosimilar to AbbVie’s Humira blockbuster and it has delivered, with a pair of pricing strategies include one though an alliance with self-labelled “disruptor” Mark Cuban.

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win FDA approval, Yuflyma (adalimumab-aaty).

Citing a list price of “\$6,576.50 per month,” the firm noted that Yuflyma was available in both auto-injector and pre-filled syringe presentations.

“The launch of Yuflyma is a critical milestone not only for Celltrion USA, but for patients, healthcare providers, and payers,” said Celltrion USA chief commercial officer Tom Nusbickel. (Also see "[Building A US Business: Celltrion’s New CCO Talks Strategy](#)" - Generics Bulletin, 28 Mar, 2023.)

“We are committed to providing a patient-centric approach with a focus on increased access to innovative, high-quality biologics in the US,” Nusbickel stated. “Celltrion has a demonstrated track record of commercial, regulatory and manufacturing success globally – including the first monoclonal antibody biosimilar infliximab – and our dedicated immunology commercial team is ready to leverage their experience and market knowledge in the US.”

Several further companies also have FDA-approved Humira biosimilars in their portfolio and are expected to launch imminently. However, as *Generics Bulletin* published, Biocon, Coherus, Fresenius Kabi and Pfizer had yet to publicly comment on their adalimumab launches.

One biosimilar that will not be among the wave of adalimumab rivals launching at the start of July is Alvotek’s AVT02 100mg/ml version, which is due to be marketed in the US by Teva. The biosimilar has repeatedly failed to pass muster with the US Food and Drug Administration as facility deficiencies led to a series of complete response letters. (Also see "[Alvotek And Teva To Miss US Adalimumab Launch After Further FDA Setback](#)" - Generics Bulletin, 29 Jun, 2023.)