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Fresenius Kabi Gets Ready To Launch Europe's First Tocilizumab Rival

Biosimilar Version Of RoActemra Receives Formal European Commission Approval

by David Wallace

Fresenius Kabi has celebrated the approval of Europe's first tocilizumab biosimilar. The rival to RoActemra is expected to be launched later this year under a settlement agreement with originator Genentech.

Fresenius Kabi has welcomed the formal approval by the European Commission of its Tyenne (tocilizumab) biosimilar rival to RoActemra, setting the stage for a launch that is expected later this year under a patent settlement with originator Genentech.

Tyenne – which has also been filed in the US (Also see "*FDA Accepts Kabi's Actemra Biosimilar – Will It Be First?*" - Generics Bulletin, 3 Aug, 2022.) – is Europe's first approved tocilizumab biosimilar. It was endorsed by the European Medicines Agency's Committee for Medicinal Products for Human Use in July, at the same time as the CHMP gave the nod to Eylea (aflibercept) and Tysabri (natalizumab) rivals from Biocon and Sandoz respectively (*see sidebar*).

Tyenne will be available as a 20mg/ml concentrate for solution for infusion and a 162mg/ml solution for injection, with

Key Takeaways:

- Tyenne is the first tocilizumab biosimilar version of RoActemra approved by the European Commission
- Fresenius Kabi received approval for the biosimilar in both subcutaneous and intravenous formulations
- Under a patent settlement with Genentech, Fresenius Kabi will be able to

the approval covering both subcutaneous (pre-filled syringe and autoinjector) and intravenous administrations. Kabi pointed out that this offered a "comprehensive, alternative treatment solution for health care professionals and patients treated with tocilizumab in Europe."

The biosimilar has been approved to treat various inflammatory and immune mediated conditions, including rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and cytokine release syndrome, as well as for the treatment of COVID-19.

In response to queries over the firm's launch plans for Tyenne, a Fresenius spokesperson told *Generics Bulletin* that "in accordance with its patent settlement agreement with Genentech, Fresenius Kabi has the agreement to market its tocilizumab product globally commencing on the license date, which is confidential. Therefore, please understand that we cannot comment on launch dates or further details concerning our go-to-market strategies."

> market its tocilizumab product globally, beginning on an undisclosed date later this year

Triple Threat: EMA Endorses Three First-Time Biosimilars

By David Wallace

21 Jul 2023

At an eventful European Medicines Agency committee meeting in July, three biosimilars from Biocon, Sandoz and Fresenius Kabi have become the first for each respective molecule – aflibercept, natalizumab and tocilizumab – to gain the endorsement of the CHMP.

Read the full article here

The firm has previously indicated that a launch is expected in the "late 2023" timeframe, with Kabi's management last year confirming that the company was "moving ahead as planned for launch in 2023" in both Europe and the US.

> ***"We are fully committed to becoming a significant player in the biopharma field."***

Pierluigi Antonelli, CEO of Fresenius Kabi, said the firm was "proud to be the first company to receive the marketing authorization for a tocilizumab biosimilar from the European

Commission."

Kabi's success with Tyenne – the company's third approved biosimilar in Europe after Idacio (adalimumab) and Stimufend (pegfilgrastim) – was "an important milestone on our pathway to consistently broadening our biopharma portfolio in the EU and worldwide," Antonelli underlined.

"In line with our Vision 2026 growth strategy," the CEO added, "we are fully committed to becoming a significant player in the biopharma field and offering essential treatment options for patients globally."

Meanwhile, Fresenius Kabi biopharma president Michael Schönhofen said that "being on the cutting edge of proposing an affordable, high-quality, and safe tocilizumab treatment option to health care providers and patients living with autoimmune diseases is an exciting step in our mission to provide access to alternative treatment options."

"Tyenne is our latest product in our expanding biosimilars portfolio for autoimmune and oncology related diseases, confirming our Vision 2026 commitments for biopharmaceuticals within Fresenius Kabi," Schönhofen summarized. "Improving the quality of patients' lives around the world, while easing the burden on health care systems, will continue to establish us as a trustworthy and reliable partner."

In an exclusive interview, Schönhofen recently spoke to *Generics Bulletin* in detail about Fresenius Kabi's biosimilars strategy. (Also see "*'You Have To Play On A Pretty Broad Part Of The Piano': Fresenius Kabi On Biosimilar Commitment*" - Generics Bulletin, 20 Jul, 2023.)

Other Developers Chase Tocilizumab

Other biosimilar versions of tocilizumab in the works include the BIIB800 candidate from Biogen and Bio-Thera Solutions, which has also been filed in both Europe and the US. (Also see "*Biogen's RoActemra Biosimilar Begins EU Approvals Process*" - Generics Bulletin, 7 Oct, 2022.) (Also see "*US Tocilizumab Race Heats Up As Biogen Matches Kabi's Filing*" - Generics Bulletin, 12 Dec, 2022.)

Meanwhile, Celltrion is also in the race for tocilizumab biosimilars, unveiling positive Phase I data for its CT-P47 candidate midway through this year. (Also see "*Celltrion Makes Tocilizumab Progress With Positive Data At EULAR 2023*" - Generics Bulletin, 1 Jun, 2023.)

Dr Reddy's also revealed positive Phase I results for its own biosimilar tocilizumab candidate earlier this year. (Also see "*Dr Reddy's Takes Another Step Forward On Tocilizumab*" - Generics Bulletin, 7 Jun, 2023.)

Gedeon Richter is also developing a biosimilar Actemra/RoActemra product, in collaboration

with Taiwan's Mycenax. (Also see "*Gedeon Richter Gearing Up For Denosumab And Tocilizumab*" - Generics Bulletin, 25 Aug, 2020.)

Meanwhile, Theramex and Alkem's Enzene Biosciences have also previously disclosed plans to partner to commercialize tocilizumab in Europe, the UK, Switzerland, and Australia. (Also see "*Theramex And Enzene Continue Alliance With Deal For RoActemra Rival*" - Generics Bulletin, 5 Jan, 2022.)