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Not In 2023 After All? FDA Turns Down Approval For Coherus' On-Body Pegfilgrastim

Coherus Says Complete Response Letter 'Solely' Due To Issue With Third-Party Filler

by Dean Rudge

Coherus BioSciences says that it will work closely with the US Food and Drug Administration and the unnamed third-party filler to obtain approval for its proposed version of Neulasta Onpro on-body injector "as quickly as possible."

Coherus BioSciences will have to wait a little longer to compete against Amgen's Neulasta (pegfilgrastim) Onpro on-body injector device after the company received a complete response letter denying US approval for its proposed rival version using Coherus' Udenyca (pegfilgrastim-cbqv) biosimilar.

The CRL almost certainly means that the company will not meet its forecasted timeline for the proposed on-body device. Earlier this month Coherus had explained that its application was "proceeding apace. We remain confident of approval for that and stay with our guidance that it will be approved and launched by the end of this year."

Announcing the setback, the California-based player explained that the CRL was "solely due to an ongoing review of inspection findings at a third-party filler," and did not identify any issues with the Udenyca on-body clinical efficacy or safety, trial design, labeling, drug substance manufacturing, or device design or manufacturing.

"No additional data or trials have been requested," Coherus has underlined, adding that it is "committed to working closely with the US Food and Drug Administration and the third-party

filler to bring Udenyca on-body to cancer patients requiring pegfilgrastim treatment as quickly as possible."

After rolling out its prefilled syringe formulation of pegfilgrastim in 2019, Coherus in March this year announced FDA approval for a single-dose, prefilled autoinjector presentation of Udenyca (pegfilgrastim-cbqv) – a feat the company labelled the "first innovation in the [US] pegfilgrastim space in eight years." (Also see "*Coherus Pulls A Rabbit Out Of The Hat With Inventive Pegfilgrastim Form*" - Generics Bulletin, 7 Mar, 2023.)

"We are currently the only team with a prefilled syringe and an autoinjector; and soon we'll be the only team with those two presentations plus an on-body [presentation]," Coherus' chairman, president and CEO Denny Lanfear had commented at the H.C. Wainwright Global Investment Conference on 12 September.

Lanfear said that it was "important to keep in mind that all three of these presentations serve different needs, and we feel that being the brand with all three is really the best position to dominate the pegfilgrastim market. We look forward to doing that next year."

Coherus had disclosed a biologics license application filing for Udenyca on-body at the beginning of this year, marking the next step for the company to launch into what it described as "its own market in a lot of different ways." (Also see "*Coherus Files On-Body Pegfilgrastim, Says 'People Talk' On Potential Rivals*" - Generics Bulletin, 16 Jan, 2023.)

At the time, the company disclosed that it was "confident that we will get approval in 2023," adding that approval would be "a very important development because it addresses a key part of the market, which is in excess of 40%."

Barclays Research put the figure slightly higher, stating in a recent note that Onpro retained "~50% share of the overall pegfilgrastim market."

Sandoz's Ziextenzo Version Said To Take Lead

With around 600,000 Neulasta Onpro units shifted annually, "it's ripe for competition," commented the firm. "The marketplace is hungry for an alternative to a brand that they've only had to use for several years now."

"And we'll be able to compete on, I think, both device differentiation as well as economic. So, that total value proposition will be compelling for our customers."

Moreover, Coherus emphasized its belief that it was at that time "the only team that's actually published pharmacokinetic data on this product."

“Pegfilgrastims are notoriously variable with their PK, [it’s] very, very difficult to achieve. They’re even difficult to achieve with prefilled syringes head-to-head,” the company said, adding: “It took us two go-rounds to get it right ourselves.”

While “eventually other [competitors] will show up,” given the “overall market dynamics, pricing difficulty, the PK, I don't know if there’s going to be other teams showing up with an on-body device in the near future or not. People talk,” Lanfear said, “but I think we’re the only people walking around with a device and PK data.”

In the crowded pegfilgrastim market, Berenberg observed in a 14 September note that Sandoz’s Ziextenzo (pegfilgrastim-bmez) “despite its later launch…now holds a 16% share of pegfilgrastim in the US market helped by competitive pricing. We believe [it is] second only to the Neulasta Onpro branded device version of the drug.”

Neulasta global revenues were $1.1bn in 2022, with 85% generated in the US, according to Berenberg. The figure is expected to fall to $353m by 2028 (78% generated in the US) by 2028 it said, citing EvaluatePharma estimates.