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Amgen Confirms US Aflibercept Filing As Regeneron Awaits Biocon Trial Fate

Key Exclusivity In May 2024, But Feeling Is That H2 2025 Launch More Likely

by Dean Rudge

Amgen has thrown its hat in the ring to launch a US biosimilar to Regeneron's Eylea eye-disease blockbuster, as all eyes remain on the outcome of a key patent-infringement trial between Biocon and the originator.

As the clock ticks closer potentially on one of the largest biologic opportunities in the US in the current decade, *Amgen* has confirmed that the US Food and Drug Administration has accepted for filing its ABP 938 proposed biosimilar to Eylea (aflibercept) 2mg.

The California-based biotech had earlier unveiled positive results from its Phase III comparison trial for ABP 938 in patients with neovascular age-related macular degeneration.

Amgen's study, which involved 576 patients with wet AMD and wrapped up at the beginning of this year, "confirmed no clinically meaningful differences in efficacy, safety, and immunogenicity" compared with Eylea.

Regulatory exclusivity for 2mg Eylea expires on 17 May 2024, allowing for biosimilar approvals thereafter. However, some analysts have projected that biosimilars will not enter the market until 2025.

In the race to launch a biosimilar to Eylea, which currently enjoys annual sales of more than $6bn in the US alone, several biosimilar sponsors are moving towards potential regulatory approval.

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Formycon recently disclosed a target action date in next June from the FDA for its FYB203 aflibercept candidate, which is due to be marketed in the US by Coherus Biosciences (*see sidebar*).

Another filer, Biocon (having acquired Viatris' biosimilar business), announced its application more than two years ago, with a lawsuit for patent infringement by the originator following in August last year. (Also see "*Viatris Believes Eylea Biosimilar Candidate Is First To Reach US FDA's Desk*" - Generics Bulletin, 10 Nov, 2021.)

Regeneron's management commented during the firm's 2 November earnings call: "We've had a trial in West Virginia, a bench trial, and we are waiting for a decision from the judge."

Formycon Gets Date For Aflibercept Filing In US

By David Wallace

29 Aug 2023

Formycon has announced a June 2024 FDA action date for its FYB203 proposed aflibercept biosimilar rival to Eylea, which is due to be marketed by Coherus in the US.

Read the full article here

In June this year, shortly ahead of trial, the court rejected motions from both sides for summary judgment, finding that "genuine disputes regarding material facts exist in this case, to the extent that summary judgment for either party is inappropriate under Rule 56 of the Federal Rules of Civil Procedure."

"It's out of our control. [A decision] will come as soon as it comes," Regeneron has insisted. "It's been several months, so it could come soon or not. It's one of those things where it's really beyond our ability to predict and control."

Pressed further, Regeneron CEO Leonard Schleifer admitted: "There are a couple of key patents that are involved in this case that relate both to formulation as well as dosing. The base case, we're assuming for us, is that the exclusivity will expire in May [2024], but we will see what happens in the litigation. Thich could be an upside obviously for the franchise."

Raymond James presented more color, outlining in a 2 November note: "Our understanding of the litigation is a ruling that upholds one of the two patents related to dosing of Eylea could bring manufacturers of potential aflibercept biosimilars to negotiation of a controlled launch during 2025."

"If the formulation patent is deemed valid. the protection may be specific to the Viatris biosimilar, but could protect against a launch of the biosimilar through the end of the decade," the investment bank added.

Raymond James also pointed to third-party analysis by IPD Analytics, which "expressed the belief that, although a close call, Regeneron has the advantage against Viatris on all three patents."

"Our base case," Raymond James noted, "is that some claims of the three patents are upheld and allow Regeneron to negotiate a controlled biosimilar launch during the second half of 2025."

Biocon has commented previously: "We remain quite confident and we feel good about how things have progressed," but would not say more with the case ongoing. The Indian firm has also revealed that it "will be looking forward to interchangeability" for its biosimilar aflibercept product.

As Eylea nears the end of its lifecycle in the US, Regeneron is banking on a high-dose version of the drug, Eylea HD, which brought in sales of $43m for the quarter. The FDA approved Eylea HD on 18 August. (Also see "*Regeneron Expands Bispecifics, Gene Therapy Programs As Exec Hints At More Deals*" - Scrip, 2 Nov, 2023.)

The originator's management told the company's same-day earnings call that early launch indicators for Eylea HD had been "very positive," with "extremely high" physician enthusiasm before launch, with early use in a broad range of patients with wet AMD and diabetic eye disease.

"It is noteworthy that physicians are prescribing Eylea HD in recalcitrant, switch and naïve patients," Regeneron said. "We are already hearing anecdotal case reports from physicians whose recalcitrant patients are returning."