

Biocon debuts aflibercept biosimilar in US

Last year, Biocon entered into a settlement and licensing agreement with the drug's patent owner Regeneron, who had previously sued the company for alleged patent infringement.



Mumbai: Bengaluru-based Biocon announced the commercial launch of Yesafili , a biosimilar of blockbuster eye disease therapy aflibercept, in the US.

Last year, Biocon entered into a settlement and licensing agreement with the drug's patent owner Regeneron, who had previously sued the company for alleged patent infringement.

The agreement allowed Biocon to launch its product in the second half of 2026. The terms of the settlement and other financial considerations were not disclosed by the company.

Yesafili was approved and granted interchangeable designation by the US FDA in May 2024.

The approval was backed by data from the Phase 3 INSIGHT trial, which demonstrated no clinically meaningful differences between Yesafili and Eylea across pharmacokinetics, safety, efficacy, and immunogenicity parameters.

“The launch of Yesafili in the US marks an important step in strengthening our presence in ophthalmology and builds on our FDA approval as one of the first interchangeable biosimilars to Eylea,” said Shreehas Tambe, CEO & MD, Biocon.

Biocon had been eagerly awaiting the commercial rollout of Yesafili in the US, viewing it as a key growth driver in the market, which roughly accounts for over 60 per cent of its total biosimilars revenue and is also expected to cushion the impact of industry-wide erosion of Revlimid (lenalidomide) contributions.

In India, Ahmedabad-based Zydus Lifesciences markets a aflibercept biosimilar under the brand name Anyra. Hyderabad-based Aurobindo Pharma’s biosimilars arm, CuraTeQ Biologics, is also developing an aflibercept biosimilar, which is currently in the Phase 3 clinical stage.

Aflibercept is a vascular endothelial growth factor (VEGF) inhibitor, that helps stop the growth of abnormal blood vessels, by blocking VEGF– a signalling protein—reduce swelling, leakage, and further damage.

In 2025, aflibercept marketed under the brand name, Eylea reported total sales of over \$4.3 billion, down 27 per cent from the previous year, as the drug encountered the impact of emerging biosimilar competition.

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