USFDA gives nod to Sandoz's biosimilar to treat eye disorder

This approval follows the acquisition of the Cimerli (ranibizumab-eqrn) business by Sandoz in the US earlier in 2024.

The FDA granted approval based on the totality of evidence.

Sandoz, a key player in generic and biosimilar medicines, on Monday, announced that the US Food and Drug Administration (FDA) has approved Enzeevu (aflibercept-abzv) 2 mg vial kit and pre-filled syringe for intravitreal injection.

According to the company's statement, Enzeevu is indicated to improve and maintain visual acuity in patients with neovascular age-related macular degeneration (nAMD). In addition, the FDA provisionally determined Enzeevu would be interchangeable with the reference medicine as it is currently subject to an unexpired exclusivity for the first interchangeable biosimilar products.

"nAMD, or wet AMD, continues to be a leading cause of vision impairment in patients over 50 years in North America. This condition affects millions of people, leading to significant challenges in their daily lives due to the progressive loss of central vision. The US approval of Enzeevu is a key milestone in Sandoz efforts to significantly improve the lives of patients impacted by this incurable disease," Claire D'Abreu-Hayling, Chief Scientific Officer, Sandoz, said.

Enzeevu is a key biosimilar value driver for the company and this approval is a major step in advancing the Sandoz growth strategy by further extending its leading US ophthalmology portfolio. Launch timing will be dependent on several factors, including the progress and outcome of pending or potential future related litigations or any potential settlements.

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nAMD, also known as wet AMD, is a subtype of age-related macular degeneration (AMD), which is a leading cause of vision impairment in patients over 50 years in North America.

"As sight disappears, so may a person's connection to the world. We welcome all treatment options that help maintain vision and meet the unique needs of the individual so those living with wet AMD can potentially maintain their independence longer. At this time, there is no cure for this disease and long-term treatment can be costly. Having more FDA-approved options, including biosimilars, can help make healthcare more person-centered and affordable," Jeff Todd, J.D., President and CEO of Prevent Blindness, said.

The FDA granted approval based on the totality of evidence, including comprehensive analytical and preclinical in vitro study data, as well as clinical data from the Mylight study.

This approval follows the acquisition of the Cimerli (ranibizumab-eqrn) business by Sandoz in the US earlier in 2024. The acquisition, which included field force employees, strengthened the company's leading ophthalmology portfolio in the US and created a robust platform to support the anticipated launch of Enzeevu.

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