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MEDIA RELEASE

Sandoz receives FDA approval for Enzeevu™ (aflibercept-abzv), further strengthening US biosimilar position

- Enzeevu™ (aflibercept-abzv) approved to treat neovascular age-related macular degeneration
- Further enhances leading US ophthalmology portfolio and increases access for patients
- Expected to be key biosimilar growth driver in US

Basel, August 12, 2024 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, today 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. Enzeevu™ is indicated to improve and maintain visual acuity in patients with neovascular age-related macular degeneration (nAMD).[1] 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

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.

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.[2]

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Jeff Todd, J.D., President and CEO of Prevent Blindness, said: “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.”

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.[3]

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™.

References

[1] Enzeevu™. Prescribing Information. Available at: https://prod.cms.us.sandoz.com/sites/spare37_sandoz_com/files/Media%20Documents/ENZEEVU_PI_2024_2.pdf [Last accessed: August 2024]

[2] American Academy of Ophthalmology®. Age-related macular degeneration (AMD). Available at: https://www.aao.org/eye-health/diseases/amd-macular-degeneration [Last accessed: August 2024]

[3] Arnaldo B, et al. Efficacy and safety of the proposed biosimilar aflibercept, SDZ-AFL, in patients with neovascular age-related macular degeneration: 52-week results from the Phase 3 Mylight study. Retina. 2024.

About Enzeevu™ (aflibercept-abzv)

The active ingredient in Enzeevu™ is aflibercept. Aflibercept is a recombinant fusion protein that binds to vascular endothelial growth factor A (VEGF-A) and placental growth factor (PlGF), inhibiting abnormal vessel growth. In patients with neovascular age-related macular degeneration (nAMD), aflibercept is injected into the eye to improve visual acuity and inhibit disease progression.

About Mylight study

The Mylight study (NCT04864834) was an international, multicenter, randomized, double-masked, 2-arm parallel study in 485 patients with neovascular age-related macular degeneration (nAMD), with a total duration of 52 weeks.[3] The Mylight study confirmed equivalent efficacy, as well as comparable safety and immunogenicity for Sandoz biosimilar aflibercept and reference medicine Eylea®* (aflibercept) as per Eylea®* approved treatment regimen in patients with nAMD.[3]

*Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

INDICATIONS

Enzeevu™ is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Ocular or periocular infection
Active intraocular inflammation
Hypersensitivity

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WARNINGS AND PRECAUTIONS
Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion may occur following intravitreal injections. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

ADVERSE REACTIONS
The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

This is not the complete list of all the safety information for Enzeevu™. Please see full Prescription Info for Enzeevu™.

DISCLAIMER

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 800 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2023, Sandoz recorded sales of USD 9.6 billion.

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