Prefilled Syringe of Faricimab-Svoa Approved by FDA for Leading Causes of Vision Loss

Following the previous FDA approval of faricimab-svoa to treat some of the leading causes of vision loss, the Administration has approved a single-dose prefilled syringe of the drug which could lead to safer and more efficient administration while easing patient burden.

The FDA has approved faricimab-svoa (Vabysmo; Genetech) in a 6.0 mg single-dose prefilled syringe (PFS) for the treatment of wet, or neovascular, age-related macular degeneration (AMD), diabetic macular edema (DME), and macular edema following retinal vein occlusion (RVO), according to a news release from Genetech.[1]

The PFS version of faricimab-svoa will deliver the same medicine that is available in the 6.0 mg vials in a simpler, ready-to-use format. Farcicimab-svoa was originally approved by the FDA in 2022, and over 4 million doses have since been distributed around the world.[1]

Faricimab-svoa was approved as the first and only bispecific antibody for the eye, demonstrating robust vision improvements and retinal drying in patients with wet AMD, DME, and RVO. Retinal drying is especially essential to treatment possibilities, as swelling due to excess fluid in the back of the eye is linked to blurred and distorted vision.[1]

The antibody targets and inhibits 2 signaling pathways that are linked to numerous vision-threatening retinal conditions by neutralizing angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A), according to the news release.[1]

Research is ongoing to determine the true nature of the Ang-2 pathway in retinal disease, but Ang-2 and VEGF-A are thought to contribute to vision loss by destabilizing blood vessels, causing new leaky blood vessels to form and heighten inflammation. Blocking pathways that involve Ang-2 and VEGF-A, as faricimab-svoa does, leads to stabilized blood cells.[1]

“While many retina specialists are already using Vabysmo as a first-line treatment, this new offering should make it even simpler to administer, thereby enhancing the treatment experience for both physicians and patients,” Levi Garraway, MD, PhD, Genetech’s chief medical officer and head of Global Product Development said in the news release.[1]

Positive data from the TENAYA and LUCERNE studies were the basis of faricimab-svoa’s original approval by the FDA. They were identical phase 3 studies that evaluated the efficacy and safety of the drug compared to aflibercept in 1329 individuals living with wet AMD.[2]

The results suggested that faricimab-svoa could allow patients to improve their vision with fewer treatments. Improvements in vision were similar between both treatments, but treatment with faricimab-svoa required fewer injections compared to aflibercept over a 2-year period.[2]

“With the potential to require fewer injections over time, Vabysmo continues to represent an important step forward for people with vision-threatening retinal conditions, and these data exemplify our commitment to redefining standards of care and reducing treatment burden,” Garraway said upon the FDA approval of faricimab-svoa.[2]

Over 60% of individuals receiving faricimab-svoa were able to be treated every 4 months, compared with those who needed aflibercept every 2 months. Additionally, patients treated with faricimab-svoa received a median number of 10 injections over the 2-year period, while those treated with aflibercept received a median of 15 injections over the same period.[2]

The ability of faricimab-svoa to treat some of the leading causes of vision loss with less treatments necessary than comparable drugs is essential to reducing burdens on patients. The FDA’s new approval of their PFS will lead to easier and safer treatment, in addition to more treatments being distributed to the patients who need it most.

References

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