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Novartis receives FDA approval for Beovu

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In two head-to-head clinical trials, patients on Beovu (brolucizumab) achieved vision gains that were non-inferior to aflibercept at year one with longer treatment intervals in a majority of patients

Novartis announced that the U.S. Food and Drug Administration (FDA) approved Beovu® (brolucizumab) injection, also known as RTH258 for the treatment of wet age-related macular degeneration (AMD). Beovu is the first FDA approved anti-VEGF to offer both greater fluid resolution versus aflibercept and the ability to maintain eligible wet AMD patients on a three-month dosing interval immediately after a three-month loading phase with uncompromised efficacy.

“Beovu meets our goals in clinical practice for treating wet AMD: improving vision and drying retinal fluid,” said Dr. Pravin U. Dugel, Managing Partner, Retinal Consultants of Arizona; Clinical Professor, Roski Eye Institute, Keck School of Medicine, University of Southern California; and principal investigator of the HAWK clinical trial. “With Beovu, greater fluid reduction was demonstrated through larger decreases in retinal thickness and a higher proportion of patients with drier retinas. Coupled with the potential to treat patients with quarterly injections, this approval may change the way we approach the treatment of wet AMD.”

The approval of Beovu was based on findings from the Phase III HAWK and HARRIER clinical trials, in which Beovu demonstrated non-inferiority versus aflibercept in mean change in best-corrected visual acuity (BCVA) at year one (week 48).

Wet AMD is a chronic, degenerative eye disease caused by an excess of VEGF, a protein that promotes the growth of abnormal blood vessels underneath the macula, the area of the retina responsible for sharp, central vision. Fluid that leaks out of these abnormal blood vessels disrupts the normal retinal structure and ultimately damages the macula. The Beovu molecule is engineered to deliver the highest concentration of drug, providing more active binding agents than other anti-VEGFs. By inhibiting VEGF, Beovu suppresses the growth of abnormal blood vessels and the potential for fluid leakage into the retina.

Beovu exhibited an overall safety profile comparable to aflibercept. Beovu is contraindicated in patients with ocular or periocular infections, active intraocular inflammation or with known hypersensitivity to brolucizumab or any of the excipients in Beovu. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema or severe intraocular inflammation.

With this approval, Novartis is offering BEOVU Your Way^{TM} in the U.S. This program provides personalized, one-on-one support for patients and caregivers, with access to a care specialist committed to understanding patients’ unique needs and preferences. Novartis is proud to be partnering with patient advocacy organizations to deliver educational materials for patients and caregivers, with the goal of empowering wet AMD patients to live safely and independently