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MEDIA UPDATE

New Phase III analysis demonstrates Novartis Beovu® showed improvement in best-corrected visual acuity in wet AMD patients with early persistent fluid

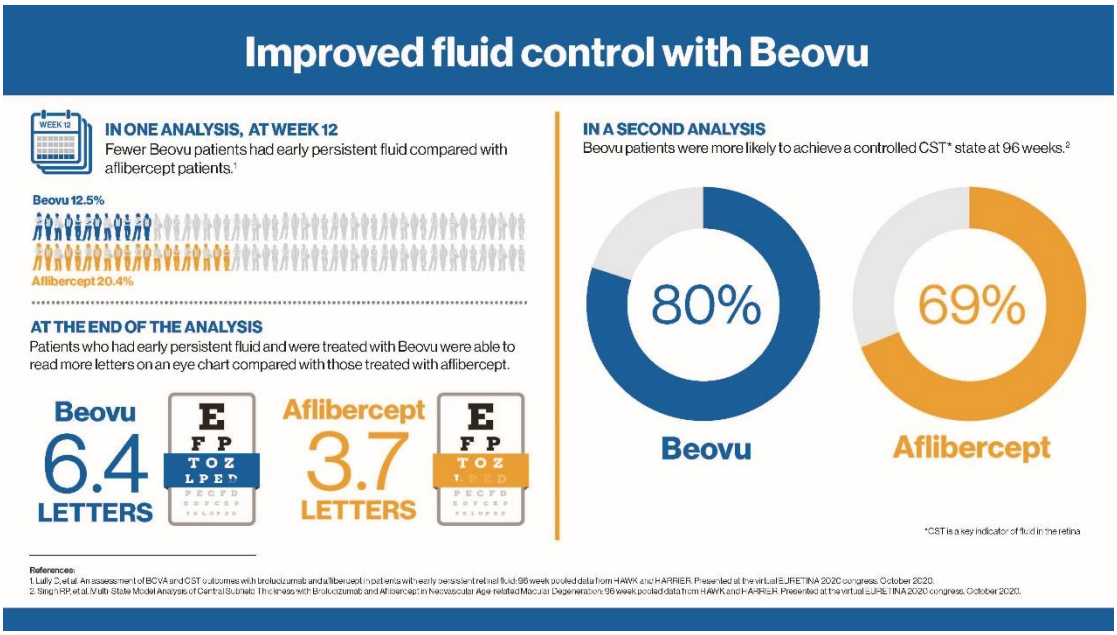
- *In a post-hoc analysis of HAWK and HARRIER, fewer Beovu (brolucizumab) patients had early persistent fluid (12.5% vs. 20.4% of aflibercept patients), defined as the presence of intra-retinal fluid and/or sub-retinal fluid through week 12 of treatment*[1]
- *Patients with early persistent fluid treated with Beovu experienced greater gains in best-corrected visual acuity (BCVA) at week 96 versus patients treated with aflibercept (6.4 vs. 3.7 letters, respectively)*[1]
- *This data, along with nine additional analyses of HAWK and HARRIER presented at EURETINA 2020 virtual congress, further support Beovu as an efficacious treatment option for wet AMD*

Basel, October 5, 2020 — Novartis today announced that results of two new post-hoc analyses of the Phase III HAWK and HARRIER clinical trials in wet age-related macular degeneration (AMD) were presented at the EURETINA 2020 virtual congress. The first analysis demonstrated fewer Beovu® (brolucizumab) patients had early persistent fluid, defined as the presence of intra-retinal fluid and/or sub-retinal fluid through week 12 of treatment, compared with aflibercept patients[1]. For patients who did have early persistent fluid, those treated with Beovu achieved greater best-corrected visual acuity (BCVA) gains and greater reductions in central subfield thickness (CST) at week 96 versus those treated with aflibercept[1].

A second analysis showed Beovu was associated with better control of retinal fluid, as measured by achievement and maintenance of defined CST levels[2]. In the study, more Beovu patients than aflibercept patients achieved CST control (80% vs. 69% at week 96 at a defined CST threshold of 320 µm, respectively)[2]. Patients who stayed longer in a controlled CST state had better visual gains compared with those who remained in an uncontrolled CST state[2]. CST is a key indicator of fluid in the retina, and drying the retina is a core aim of treatment for wet AMD[2].

“The data presented at EURETINA suggests Beovu can better help patients who have persistent retinal fluid achieve disease control by reducing CST and improving their vision in the long term,” said Dirk Sauer, Global Head Development, Novartis Pharma Ophthalmology. “These results further strengthen our confidence in Beovu as an effective and important treatment option for wet AMD patients aiming to improve their vision.”

Novartis has nine podium presentations at the congress and is sponsoring a Beovu symposium and an independent medical education program conducted by EURETINA.



About Beovu (brolucizumab)
Beovu (brolucizumab, also known as RTH258) is the first advanced humanized single-chain antibody fragment (scFv) approved for clinical use[3-5]. Single-chain antibody fragments are highly sought after in drug development due to their small size, enhanced tissue penetration, rapid clearance from systemic circulation and drug delivery characteristics[5-7].

The proprietary innovative structure results in a small molecule (26 kDa) with potent inhibition of, and high affinity to, all VEGF-A isoforms[6]. Beovu is engineered to deliver a high concentration of drug, thus providing more active binding agents[3-5]. In preclinical studies, Beovu inhibited activation of VEGF receptors through prevention of the ligand-receptor interaction[6-8]. Increased signaling through the VEGF pathway is associated with pathologic ocular angiogenesis and retinal edema[9]. Inhibition of the VEGF pathway has been shown to inhibit the growth of neovascular lesions and suppress endothelial cell proliferation and vascular permeability[9].

Beovu is approved in more than 40 countries, including in the US[10], EU[11], UK[11], Japan[12], Canada[13] and Australia[14], based on the results of the HAWK and HARRIER clinical trials.

About the HAWK and HARRIER studies
With more than 1,800 patients across nearly 400 centers worldwide, HAWK (NCT02307682) and HARRIER (NCT02434328) are the first global head-to-head trials in patients with wet AMD that prospectively demonstrated efficacy of Beovu at week 48 using an innovative q12w/q8w regimen, with a majority of patients on q12w immediately following the loading phase[3,4]. Both studies are 96-week prospective, randomized, double-masked multi-center studies and part of the Phase III clinical development of Beovu[3,4]. The studies were designed to compare the efficacy and safety of intravitreal injections of brolucizumab 6 mg (HAWK and HARRIER) and 3 mg (HAWK only) versus aflibercept 2 mg in patients with wet AMD[3,4]. The most common adverse events (≥5% of patients) with Beovu were vision blurred, cataract, conjunctival hemorrhage, vitreous floaters and eye pain[3,4].

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About Novartis

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