

## **MEDIA & INVESTOR RELEASE**

# **Novartis reports one year results of Phase III MERLIN study evaluating Beovu® every four week dosing and provides update on Beovu clinical program**

- *Beovu (brolucizumab) met MERLIN's primary endpoint of non-inferiority in change in best corrected visual acuity from baseline and superiority on anatomical secondary endpoints at year one versus aflibercept when given every four weeks following the loading phase<sup>1</sup>*
- *In this study evaluating every four week dosing, Beovu was associated with higher rates of IOI including retinal vasculitis and retinal vascular occlusion versus aflibercept<sup>1</sup>*
- *Patient safety is of paramount importance and led Novartis to decide on early termination of the MERLIN study*
- *Novartis has also decided on early termination of the RAPTOR and RAVEN studies, which assessed the efficacy and safety of brolucizumab in retinal vein occlusion, and included six initial monthly injections*
- *Novartis has proactively communicated these data to health authorities and will pursue an update to the Beovu prescribing information globally regarding every four week dosing*
- *When used on a two- to three-month interval following the loading phase, Beovu remains an important and effective treatment option for appropriate patients with wet AMD<sup>2,3</sup>*

**Basel, May 28, 2021** — Today, Novartis reported the first interpretable year one results of the Phase III MERLIN study, a two-year study initiated in H2 2018, assessing the efficacy and safety of Beovu® (brolucizumab) 6 mg versus aflibercept 2 mg given every four weeks following the loading phase in patients with wet age-related macular degeneration (AMD) who have persistent retinal fluid despite anti-VEGF therapy.

Beovu met MERLIN's primary endpoint of non-inferiority in change in best corrected visual acuity from baseline and superiority on select anatomical secondary endpoints at year one versus aflibercept when given every four weeks following the loading phase<sup>1</sup>. However, given every four weeks in MERLIN, IOI including RV, and RO were reported with a higher frequency in the Beovu 6 mg every four weeks arm when compared to aflibercept 2 mg every four weeks (IOI: 9.3% vs 4.5% of which RV: 0.8% vs 0.0%; RO: 2.0% vs 0.0%).<sup>1</sup> The overall rate of

vision loss (15 letters or more) due to all causes was 4.8% in the Beovu arm and 1.7% in the aflibercept arm<sup>1</sup>.

“Although longer dosing intervals may benefit many people living with wet AMD and other retinal diseases, some are in need of monthly dosing to address persistent fluid. We initiated MERLIN and other clinical programs to explore Beovu for these patients,” said John Tsai, MD, Global Head of Drug Development and Chief Medical Officer, Novartis. “These data help inform our trials moving forward, so we can best determine how appropriate patients can benefit most from this important medicine.”

Novartis evaluated all ongoing brolocizumab clinical programs assessing studies with four week dosing intervals after the loading phase. In the interest of patient safety, Novartis has decided to terminate the MERLIN study and the RAPTOR and RAVEN studies, which were assessing the efficacy and safety of brolocizumab with six initial monthly injections in retinal vein occlusion. All other relevant ongoing trial protocols will be amended to discontinue four week dosing intervals after the loading phase. Clinical trial investigators have been informed and will appropriately follow up with their patients. Physicians should not treat patients with Beovu 6 mg at intervals less than two months beyond the first three doses.

Novartis has proactively communicated these data to health authorities and will pursue an update to the Beovu prescribing information globally.

When used on a two- to three-month interval following the loading phase, Beovu continues to be an important and effective treatment option for appropriate patients with wet AMD<sup>2,3</sup>. Novartis remains committed to supporting the retina community with information regarding Beovu. Beovu is contraindicated in patients with ocular or periocular infections, active intraocular inflammation or known hypersensitivity to brolocizumab<sup>4</sup>.

Further analysis of the clinical data from MERLIN is ongoing, and detailed data will be presented at an upcoming medical meeting. Novartis has a strong ongoing commitment to Ophthalmology and to bringing innovative treatments to patients with or at risk of developing eye conditions where there is a high unmet need.

### **About wet AMD**

Wet AMD is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America, Europe, Australia and Asia, impacting an estimated 20 million people worldwide<sup>5-7</sup>. Wet AMD occurs when abnormal blood vessels form underneath the macula, the area of the retina responsible for sharp, central vision<sup>8-10</sup>. These blood vessels are fragile and leak fluid, disrupting the normal retinal architecture and ultimately causing damage to the macula<sup>8-10</sup>.

Early symptoms of wet AMD include distorted vision (or metamorphopsia) and difficulties seeing objects clearly<sup>11</sup>. Prompt diagnosis and intervention are essential. As the disease progresses, cell damage increases, further reducing vision quality<sup>12</sup>. This progression can lead to a complete loss of central vision, leaving the patient unable to read, drive or recognize familiar faces and potentially depriving them of their independence<sup>12,13</sup>. Without treatment, vision can rapidly deteriorate<sup>14</sup>.

### **About Beovu (brolocizumab)**

Beovu (brolocizumab, also known as RTH258) is approved for the treatment of wet age-related macular degeneration (AMD) in more than 60 countries, including in the US, EU, UK, Japan, Canada and Australia<sup>4,15-18</sup>. Additional trials, which study the effects of brolocizumab in patients with wet AMD, diabetic macular edema (DME), and proliferative diabetic retinopathy (PDR), are currently ongoing.

## About Novartis in Ophthalmology

At Novartis, our mission is to discover new ways to improve and extend people's lives. In ophthalmology, we develop and deliver life-changing medicines and therapies for diseases and conditions from front to back of the eye, enabled by data and transformative technologies. Our ophthalmic solutions reach more than 150M people per year, from premature infants to the elderly.

## Disclaimer

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## About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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