MEDIA & INVESTOR RELEASE

Novartis Phase III Beovu® data show potential for fluid resolution in more diabetic macular edema patients with fewer injections versus aflibercept

• In KESTREL and KITE, Beovu (brolucizumab) 6 mg met the primary endpoints of non-inferiority in change in best corrected visual acuity from baseline versus aflibercept 2 mg at year one in diabetic macular edema (DME) patients!

• More patients treated with Beovu 6 mg experienced fluid (IRF/SRF) resolution at week 32 and week 52 versus aflibercept; fluid is a key marker of disease activity in DME!

• Beovu demonstrated an overall well-tolerated safety profile in KESTREL and KITE!

• Phase III KESTREL and KITE trials are the first pivotal trials to assess an anti-VEGF on six-week dosing intervals in the loading phase, suggesting Beovu may offer fewer injections from the start of treatment!

• Novartis is committed to bringing Beovu 6 mg to DME patients and will submit data from KESTREL and KITE to global health authorities in H1 2021

Basel, May 1, 2021 — Novartis today announced positive one-year results of the Phase III KESTREL and KITE* studies, evaluating the efficacy and safety of Beovu® (brolucizumab) 6 mg in diabetic macular edema (DME). Both studies met their primary endpoints of non-inferiority in change in best corrected visual acuity (BCVA) from baseline for Beovu 6 mg versus aflibercept 2 mg at year one! In KESTREL, patients on Beovu 6 mg gained a mean of 9.2 letters versus 10.5 letters for patients on aflibercept 2 mg! In KITE, patients on Beovu 6 mg gained a mean of 10.6 letters versus 9.4 letters for patients on aflibercept 2 mg! These results will be presented at the Association for Research in Vision and Ophthalmology (ARVO) 2021 Annual Meeting.

In pre-specified secondary endpoints, fewer eyes treated with Beovu had intraretinal and/or subretinal fluid (IRF/SRF) at week 32 (first assessment of disease activity) and week 52 versus eyes treated with aflibercept! More eyes treated with Beovu 6 mg than eyes treated with aflibercept achieved central subfield thickness (CSFT) levels below 280 μm at weeks 32 and 52!, Fluid is a key marker of disease activity in DME and CSFT is a key indicator of fluid in the retina!.

“Treatment for diabetic macular edema is a high unmet medical need in the US and globally. Our goal as physicians is to work on preventing blindness for the significant proportion of
related macular degeneration (AMD). Beovu (brolucizumab, 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. Additional trials, which study the effects of brolucizumab in patients with wet AMD, DME, retinal vein occlusion (RVO) 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.

*Kite Pharma, Inc. is neither a sponsor nor associated with Novartis' KITE trial.*

**Disclaimer**

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products.

You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

**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](https://www.novartis.com).

Novartis is on Twitter. Sign up to follow @Novartis at [https://twitter.com/novartisnews](https://twitter.com/novartisnews)

For Novartis multimedia content, please visit [https://www.novartis.com/news/media-library](https://www.novartis.com/news/media-library)

For questions about the site or required registration, please contact media.relations@novartis.com
References


# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Peter Zuest
Novartis External Communications
+ 41 79 899 9812 (mobile)
peter.zuest@novartis.com

Amy Wolf
Novartis Division Communications
+ 41 79 576 07 23 (mobile)
amy.wolf@novartis.com

Julie Masow
Novartis Head US External Engagement
+1 862 579 8456
julie.masow@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Sloan Simpson +1 862 778 5052