Novartis to present predictability data for brolucizumab in nAMD from pivotal HAWK and HARRIER trials at ARVO

Basel, March 28, 2018 – Novartis will present new data from the HAWK and HARRIER Phase III trials at the upcoming Association for Research in Vision and Ophthalmology (ARVO) 2018 Annual Meeting, Honolulu, April 29 – May 3. Data on a secondary endpoint examining the predictability of 12-week dosing for patients with neovascular age-related macular degeneration (nAMD) treated with brolucizumab (RTH258) will be presented for the first time at the meeting.

“We look forward to sharing additional positive findings from the Phase III HAWK and HARRIER trials about this potential new treatment for nAMD with patients and the ophthalmology community,” said Dirk Sauer, Development Unit Head, Novartis Ophthalmology.

nAMD, which affects an estimated 20-25 million people worldwide, is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America, Europe, Australia and Asia1,2. Frequent injections into the eye, a standard requirement for nAMD therapies, can be a significant hardship for patients and a burden on caregivers.

HAWK and HARRIER enrolled more than 1,800 patients with nAMD across 400 centers worldwide3. Primary endpoint findings and additional results from these head-to-head trials comparing brolucizumab with aflibercept were presented at the American Academy of Ophthalmology 2017 Annual Meeting.

Following are abstracts to be presented by Novartis at ARVO 2018 based on pre-specified endpoints of HAWK and HARRIER:

- Predictability of the 12-week dosing status at Week 48 for patients receiving brolucizumab in HAWK and HARRIER [C0017; April 30, 8:15 – 10:00 AM]
- Comparative assessment of anatomical outcomes for nAMD patients treated with brolucizumab and aflibercept: 16-week data from the HAWK and HARRIER studies [C0026; April 30, 8:15 – 10:00 AM]
- Phase III prospective studies of brolucizumab versus aflibercept in nAMD: 48-week primary and key secondary outcomes from HAWK and HARRIER [1624; April 30, 12:45 – 1:00 PM]

About brolucizumab (RTH258)

Brolucizumab (RTH258) is a humanized single-chain antibody fragment (scFv) and the most clinically advanced, humanized single-chain antibody fragment to reach this stage of development. 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 characteristics3,4,5.

The proprietary innovative structure results in a molecule of small size (26 kDa) with potent inhibition of, and high affinity to, all VEGF-A isoforms1,4. In preclinical studies, brolucizumab inhibited activation of VEGF receptors through prevention of the ligand-receptor
interaction. Increased signaling through the VEGF pathway is associated with pathologic ocular angiogenesis and retinal edema. Inhibition of the VEGF pathway has been shown to inhibit the growth of neovascular lesions, resolve retinal edema and improve vision in patients with chorioretinal vascular diseases.

About HAWK and HARRIER study design
With more than 1,800 patients across 400 centers worldwide, HAWK and HARRIER are the first and only global head-to-head trials in patients with nAMD that prospectively demonstrated efficacy at week 48 using an innovative q12w/q8w regimen, with a majority of patients on q12w immediately following the loading phase. Both studies are 96-week prospective, randomized, double-masked multi-center studies and part of the Phase III clinical development of brolucizumab. Preliminary data from the two studies were presented at the American Academy of Ophthalmology Congress in November 2017.

The studies were designed to compare the efficacy and safety of intravitreal injections of brolucizumab 6 mg and 3 mg (HAWK only) versus aflibercept 2 mg in patients with nAMD. The primary efficacy objective of HAWK and HARRIER trials was to confirm that brolucizumab is noninferior to aflibercept in mean change in BCVA from baseline to Week 48. Secondary endpoints include average mean change in BCVA from baseline over the period week 36-48, the proportion of patients on a q12w interval at week 48 and anatomical parameters.

In both trials, patients were randomized to either brolucizumab or aflibercept. Immediately following the 3-month loading phase, patients in the brolucizumab arms received a q12w dosing interval with an option to adjust to a q8w dosing interval based on masked disease activity assessments at defined visits. Aflibercept was dosed bi-monthly according to its label.

Week 16 was an important pre-defined data point, as it represents a timepoint when the treatment assessment for brolucizumab and aflibercept were identical, providing an opportunity to observe how both drugs performed in a matched comparison.

About neovascular age-related macular degeneration (nAMD or wet AMD)

nAMD 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 to 25 million people worldwide. nAMD occurs when abnormal blood vessels form underneath the macula, the area of the retina responsible for sharp, central vision. These blood vessels are fragile and leak fluid, disrupting the normal retinal architecture and ultimately causing damage.

Early symptoms of nAMD include distorted vision or metamorphopsia and difficulties seeing objects clearly. Prompt diagnosis and intervention are essential. As the disease progresses, cell damage increases, further reducing vision quality. This progression can lead to a complete loss of central vision, leaving the patient unable to read, drive or recognize familiar faces. Without treatment, vision can rapidly deteriorate.

About Novartis in ophthalmology

Novartis is a leading ophthalmology company, with therapies that treat both front and back of the eye disorders, including retina diseases, glaucoma, dry eye and other external eye diseases. In 2016, approximately 200 million patients worldwide were treated with Novartis ophthalmic products.

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Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 122,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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