Novartis presents new data at EURETINA 2017 confirming Lucentis® efficacy and durability vs aflibercept

- **Interim results of the head-to-head RIVAL study confirm strong efficacy and comparable durability versus aflibercept in patients with nAMD**

- **Five-year results from the Lucentis LUMINOUS study, the largest ever in retinal disease, demonstrate real-world efficacy and safety across five retinal diseases**

**Basel, September 09 2017** – Novartis, the global leader in ophthalmology, today reported new data confirming Lucentis® (ranibizumab) efficacy and durability in patients with nAMD at the 17th EURETINA Congress in Barcelona, Spain (September 7-10, 2017). One-year interim results from the Phase IV head-to-head RIVAL study compared ranibizumab versus aflibercept using a treat-and-extend treatment regimen in patients with neovascular age-related macular degeneration (nAMD).

Additionally, five-year results from the LUMINOUS study confirm the real-world efficacy and safety of Lucentis in patients with nAMD, visual impairment due to diabetic macular edema, branch retinal vein occlusion, central retinal vein occlusion and myopic choroidal neovascularization. LUMINOUS is a real-world study assessing the long-term effects of Lucentis in more than 30,000 patients being treated across five different eye diseases in 43 countries across 494 sites, making this the largest-ever study in retinal disease. This data deepens our knowledge of how the product is being used by patients in the real world.

“We are delighted by the RIVAL data, which confirms unsurpassed efficacy of Lucentis,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Both RIVAL and LUMINOUS demonstrate our commitment to further invest in the science of this product, a standard of care in the treatment of nAMD for over a decade. We look forward to seeing the full RIVAL dataset next year.”

In data from the RIVAL study (n=278) presented today, individuals receiving the anti-vascular endothelial cell growth factor (anti-VEGF) agent Lucentis 0.5 mg, using a treat-and-extend treatment regimen, experienced clinically relevant improvements in vision, measured as Best Corrected Visual Acuity (BCVA), at 12 months. The efficacy of Lucentis was demonstrated by a 7.1 letter gain, versus a 4.9 letter gain in the aflibercept 2.0 mg arm (p=0.063), with patients in both arms receiving the same average number of injections.

Of the 30 Novartis scientific contributions at EURETINA 2017, 16 are Lucentis oral presentations, including RIVAL and four LUMINOUS study abstracts across five different retinal diseases.

**About Lucentis (ranibizumab)**

Lucentis (ranibizumab) is a humanized therapeutic antibody fragment designed to block all biologically active forms of vascular endothelial cell growth factor-A (VEGF-A). Increased levels of VEGF-A are seen in neovascular age-related macular degeneration (nAMD) and other ocular diseases such as diabetic macular edema (DME) and retinal vein occlusion (RVO). Lucentis was specifically designed for the eye, minimizing systemic exposure.
Lucentis is indicated for the treatment of nAMD, and for the treatment of visual impairment due to DME, branch retinal vein occlusion (BRVO), central retinal vein occlusion (CRVO), choroidal neovascularization (CNV) secondary to pathologic myopia (PM) and CNV associated with causes other than nAMD or pathologic myopia (PM).

Lucentis is available in more than 110 countries and has a well-established safety profile supported by a portfolio of 129 sponsored clinical studies in addition to extensive real-world experience. The safety profile of Lucentis has been well established in a clinical development program that has enrolled approximately 120,000 patients across indications and has over 4.3 million patient-treatment years of exposure since its launch in the United States in 2006. Lucentis was developed by Genentech and Novartis. Genentech has the commercial rights to Lucentis in the United States. Novartis has exclusive rights in the rest of the world.

**About the RIVAL study**
The RIVAL study is a 24-month, randomized, controlled, multi-center, Phase IV study conducted in Australia. It is the first head-to-head clinical trial designed to compare Lucentis with aflibercept in patients with neovascular age-related macular degeneration (nAMD) using the same treat-and-extend regimen.

A total of 278 treatment-naïve patients are enrolled in the RIVAL study and randomized to receive either Lucentis 0.5 mg or aflibercept 2.0 mg over the 24-month study period. Patients eligible for inclusion in the study included visual impairment of ≥23 letters on a Logarithm of Minimal Angle of Resolution (LogMAR) chart. After receiving three initial monthly injections, patients entered the treatment and extension phase of the study, whereby the treatment interval was extended by two weeks at a time to a maximum of 12 weeks.

The primary efficacy endpoint of the RIVAL study is defined as mean change in the area of geographic atrophy (GA) from baseline to month 24. Results from a pre-planned 12-month interim analysis assessed key secondary endpoints: number of injections and change in BCVA from baseline to month 12. These findings were presented at the EURETINA Congress in Barcelona on 9 September 2017. Full results of the study are anticipated in 2018.

**About the LUMINOUS study**
The LUMINOUS study is a five-year, multi-center, global, observational study designed to evaluate the long-term effectiveness, safety, and treatment patterns associated with Lucentis treatment in patients with nAMD, with visual impairment due to DME, BRVO, CRVO, and CNV in a real-world setting. It is the largest study of its kind ever conducted.

Thirty thousand adults who have previously been treated with, who were currently being treated with or are initiating treatment with Lucentis in the indications nAMD or visual impairment due to DME, BRVO, CRVO, or mCNV participated in LUMINOUS. The study was conducted in 494 sites in 43 countries.

The primary endpoints of the LUMINOUS study include mean visual acuity (VA), mean change in VA at three, six and 12 months from baseline visit, and annually thereafter; incidence rate, relationship and severity of treatment-emergent ocular and non-ocular adverse events (AEs) and mean visual acuity at quarterly intervals for the primary treated eye set.

**About Novartis in Ophthalmology**
Novartis is the 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, 200 million patients worldwide were treated with Novartis ophthalmic products.
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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,” “expect,” “anticipate,” “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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues, 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 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 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 119,000 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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