Novartis data at ARVO 2014 confirm transformational real world outcomes and highlight the safety profile of Lucentis®

- **LUMINOUS**, the largest ongoing trial in medical retina, presented 1-year results on the effectiveness and safety profile of Lucentis in patients with wet AMD¹

- **COMRADE-B** study indicates BRVO patients treated with Lucentis had significantly higher vision gains at month 6 compared with dexamethasone²

- **New real-world data demonstrates significant differences in rates of endophthalmitis with aflibercept and Lucentis**³

**Basel, May 9, 2014** – Novartis reports that considerable data on the eye drug Lucentis® (ranibizumab), first licensed in June 2006, have been presented at the 2014 Association for Research in Vision and Ophthalmology (ARVO) annual meeting this week. The work spans the five indications that Lucentis is licensed for (treatment of wet age-related macular degeneration (wet AMD), treatment of visual impairment due to diabetic macular edema (DME), branch retinal vein occlusion (BRVO), central retinal vein occlusion (CRVO) and myopic choroidal neovascularization (myopic CNV)), and highlights the effectiveness and safety profile of Lucentis through both pivotal clinical trials and real-world observational studies.

"Lucentis has already shown proven effectiveness in reducing vision loss across indications, and this is evident by the clinical trial findings presented at ARVO 2014," said Dr Timothy Wright, Global Head Development, Novartis Pharma AG. "What is key is that the efficacy and safety findings are also reflected in the real world clinical setting. The LUMINOUS 1-year interim results, for example, confirm the safety profile of Lucentis in patients with wet AMD."

**Lucentis ARVO highlights include:**

*Real-world evidence:* The LUMINOUS trial – the largest ongoing trial in medical retina to enroll 30,000 patients, is a 5-year prospective, multinational, observational study across all approved indications of Lucentis – presented 1-year results on the effectiveness and safety of Lucentis. Of the first 2,112 patients with wet AMD recruited, those prior treated patients, including those with more than 6 years of Lucentis treatment, maintained their vision in the first year of the LUMINOUS study. New Lucentis patients gained nearly a line of vision (+4.1 ETDRS letters from baseline). No new safety findings were identified¹. [Paper session 335]

*Safety profile and efficacy:* Results from the COMRADE-B study, which compared the efficacy and safety of Lucentis and dexamethasone in patients with BRVO, were reported. Patients treated with Lucentis (0.5 mg Lucentis intravitreal injections for 3 months followed by PRN dosing) compared to patients treated with dexamethasone (0.7mg implants for 6 months) had significantly higher vision gains at month 6. Both treatment groups exhibited low rates of ocular and non-ocular safety events, although there was a nine-fold higher incidence of increased intraocular pressure in the dexamethasone arm². [Poster session 239]
Wet AMD: A retrospective cohort study of the injection number, associated costs and endophthalmitis rate in patients who received Lucentis or aflibercept for wet AMD in the US from November 2011 to July 2013 were reported. The US claims data showed that there was no significant difference between first-line Lucentis and aflibercept treatment for injection frequency (5.02 and 5.04, respectively), ophthalmologist visits (6.08 and 5.24, respectively) and annual costs (USD 9,894 and USD 10,288, respectively). However there was a significantly higher rate of endophthalmitis reported in association of aflibercept injections (0.17%) compared with Lucentis (0.08%), adjusted odds ratio=2.70. [Poster session 507 – sponsored by Genentech]

About Lucentis® (ranibizumab)
Lucentis was designed to save sight and has demonstrated transformational efficacy with individualized dosing in its licensed indications. As an antibody fragment with a short systemic half-life, Lucentis was specifically designed, developed, formulated and licensed for ocular conditions, and is manufactured to the highest standards for intraocular use.

Lucentis is licensed in more than 100 countries, for the treatment of wet age-related macular degeneration (wet AMD), visual impairment due to diabetic macular edema (DME) and for visual impairment due to macular edema secondary to retinal vein occlusion (RVO), including both branch- and central-RVO. Also, Lucentis is licensed in more than 60 countries, not including the US, for the treatment of patients with visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (myopic CNV). In most countries, including those in Europe, Lucentis has an individualized treatment regimen with the goal of maximizing visual outcomes while minimizing under- or over-treating patients.

Lucentis has a well-established safety profile supported by 43 sponsored clinical studies and real-world experience. Its safety profile has been well established in a clinical development program that enrolled more than 12,500 patients across indications and there is more than 2.4 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. Lucentis is a registered trademark of Genentech Inc.

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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, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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References
2. Hattenbach L-O. Efficacy and Safety of 0.5 mg Ranibizumab compared with 0.7 mg dexamethasone intravitreal implant in patients with branch retinal vein occlusion over 6 months: The COMRADE-B study. ARVO 2014.

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