Novartis drug Lucentis approved in EU as first effective anti-VEGF treatment for myopic choroidal neovascularization

- **Lucentis®** (ranibizumab) is the first licensed therapy to improve vision in patients with visual impairment due to choroidal neovascularization secondary to pathologic myopia.

- Pivotal trial shows average visual acuity improvement of up to 14 letters at one year with a median of only two injections with Lucentis treatment.

- Myopic CNV, the growth of abnormal leaky blood vessels in the back of the eye in high myopia, often causes irreversible deterioration of central vision.

**Basel, July 5, 2013** – The European Commission has granted Novartis a new indication for **Lucentis®** (ranibizumab) to treat patients with visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (myopic CNV). This makes Lucentis, specifically designed for the eye and proven to save sight, the first anti-VEGF therapy licensed for four indications in the European Union. Pathologic myopia often affects working-age adults and is a major cause of vision loss worldwide, with 1-3% of the general population. CNV is the most common vision-threatening complication of high myopia. In patients with untreated myopic CNV the long-term prognosis is poor with approximately 90% of affected patients developing severe vision loss after five years. The resulting visual loss from myopic CNV which usually affects people younger than 50 years old has a profound effect on productivity, financial status, career expectations, and quality of life in working-age individuals.

According to the European label, treatment of myopic CNV starts with a single injection. Any further injections are based on an individualized regimen. Retreatment is based on vision and anatomical changes, and monitoring is required monthly for the first two months and then at least quarterly up to one year; in the second year monitoring is at the discretion of the treating physician.

RADIANCE, the Novartis-sponsored clinical trial in patients with myopic CNV, shows that Lucentis provides rapid and superior improvement in visual acuity compared with the current licensed standard of care, Visudyne® (verteporfin PDT). There is an average 14-letter visual acuity gain in the first year with a median of 2 injections and over 60% of patients in RADIANCE did not need any further injections after 6 months.

“We are committed to fully understanding medical retina and to serving unmet patient needs. This fourth indication for our pioneering ophthalmology drug, Lucentis, shows how far we have come since it was first launched in 2006,” said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. “We expect that the use of Lucentis will significantly change the treatment of myopic CNV, as it is the first and only licensed treatment that has been proven to restore vision in patients with visual impairment due to myopic CNV.”
Rapid visual acuity gains were achieved after only a single Lucentis injection and more than 70% of patients treated with Lucentis in RADIANCE experienced a reduction in CNV leakage and intraretinal edema, with central retinal thickness being significantly reduced from as early as month one.

Lucentis has a well-established safety profile and its safety profile in RADIANCE was consistent with that observed in other studies, as well as in real-world experience, and no new ocular/non-ocular safety risks were identified.

**About Lucentis® (ranibizumab)**
Lucentis 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 wet AMD 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 licensed for the treatment of wet AMD in more than 100 countries, in more than 90 countries for the treatment of visual impairment due to DME and in 90 countries for visual impairment due to macular edema secondary to RVO, including both branch- and central-RVO. In many 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 extensive 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 1.7 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.

Novartis sponsors the eXcellence in Ophthalmology Vision Award (XOVA). XOVA is an annual award launched in 2010 that provides funding to non-profit initiatives and projects that will have a positive impact on improving the quality of eye care and make a significant impact in addressing unmet needs in the fields of ophthalmology and optometry.

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The foregoing release contains forward-looking statements that can be identified by terminology such as “committed,” “expect,” “will,” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Lucentis or regarding potential future revenues from Lucentis. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Lucentis to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Lucentis will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Lucentis will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Lucentis could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected manufacturing issues; the impact that the foregoing factors could have on the values
attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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References

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