Novartis’ Lucentis® received EU approval in new indication – Lucentis the only treatment available for a wide range of CNV conditions

- The European Commission approved Lucentis to treat patients for visual impairment due to choroidal neovascularization (CNV) associated with causes other than neovascular age-related macular degeneration (nAMD) or secondary to pathologic myopia (PM)
- Results of the pivotal MINERVA study showed a significant gain in visual acuity of approximately 10 letters at two months, which was maintained for one year
- Lucentis (ranibizumab) is the first and only treatment approved in this indication in the EU, and the only treatment available for a wide range of CNV conditions

Basel, December 7, 2016 – Novartis today announced that the European Commission (EC) has granted an additional indication for Lucentis® (ranibizumab) to treat patients with visual impairment due to choroidal neovascularization (CNV) associated with causes other than neovascular age-related macular degeneration (nAMD), or secondary to pathologic myopia (PM). With this approval, Lucentis is the first retinal treatment approved for these conditions, addressing an important unmet medical need.

“This confirms Lucentis as standard of care in diseases of the retina,” said Paul Hudson, CEO Novartis Pharmaceuticals. “With this approval, Lucentis is the only treatment available for a wide range of CNV conditions. We are dedicated to bringing new innovations to the market, as we are aware that there is still high unmet medical need for patients with retinal diseases.”

The approval is applicable to all 28 European member states, as well as Iceland, Liechtenstein and Norway. It was based on the positive opinion from the Committee for Medicinal Products for Human Use (CHMP), adopted in October 2016. Following this approval, Lucentis covers six indications in Europe.

Submissions for this indication have been filed in 11 other countries, including Switzerland, Australia, Indonesia and Brazil.

About CNV
CNV is an ocular condition caused by the growth of abnormal blood vessels below the retina, which cause disruption to vision. The condition can occur rapidly, and is a major cause of vision loss, causing symptoms including visual distortion, color disturbances, partial loss of vision or a blindspot within the visual field. CNV is most commonly associated with neovascular (“wet”) age-related macular degeneration and pathologic myopia, but it can also occur with many other conditions including uveitis, central serous chorioretinopathy, angiod streaks, trauma, retinal or macular dystrophies, and with no apparent cause (idiopathic CNV).
About MINERVA study trial
The submission was supported by data from the Novartis sponsored MINERVA study, which showed that Lucentis treatment resulted in a significant gain of visual acuity by approximately 10 letters at two months; this gain was maintained to month 12 of the one-year study. Ranibizumab has therefore proven to be effective for the treatment of CNV, regardless of the underlying etiology, with no new safety findings.

About Lucentis
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 nAMD and other ocular diseases such as DME and retinal vein occlusion (RVO). Lucentis was specifically designed for the eye, minimizing systemic exposure.

Lucentis is licensed for the treatment of nAMD, and for the treatment of visual impairment due to CNV, DME, BRVO and CRVO. The indication for the treatment of visual impairment due to CNV includes secondary to pathologic myopia (PM) and CNV associated with causes other than nAMD or PM (approved in EMA only).

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 more than 76,000 patients across indications and has 3.7 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.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “dedicated to,” “positive opinion,” “so far,” or similar terms, 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 are based on the current beliefs and expectations of management 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 Lucentis will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Lucentis will be commercially successful in the future. In particular, management’s expectations regarding Lucentis could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain proprietary intellectual property protection; global economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected 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, eye care and cost-saving generic...
pharmaceuticals. Novartis is the only global company with leading positions in these areas. In
2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group
amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and
amortization charges). Novartis Group companies employ approximately 118,000 full-time-
equivalent associates. Novartis products are available in approximately 180 countries around
the world. For more information, please visit http://www.novartis.com.

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