Novartis' ranibizumab receives EU approval in new indication – Ranibizumab the only treatment available for a wide range of CNV conditions

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- *The European Commission approved ranibizumab 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*
- *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 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, ranibizumab is the first retinal treatment approved for these conditions, addressing an important unmet medical need.

"This confirms ranibizumab as standard of care in diseases of the retina," said Paul Hudson, CEO Novartis Pharmaceuticals. "With this approval, ranibizumab 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, ranibizumab 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 vison 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, angioid 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 ranibizumab 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 ranibizumab

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

Ranibizumab 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.

Ranibizumab 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 ranibizumab 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. Ranibizumab was developed by Genentech and Novartis. Genentech has the commercial rights to ranibizumab in the United States. Novartis has exclusive rights in the rest of the world. ranibizumab is a registered trademark of Genentech Inc.

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 more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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