Novartis shows continued commitment in Japan with Lucentis® approval in fourth Japanese indication, diabetic macular edema

- Lucentis is the first anti-VEGF therapy approved for diabetic macular edema (DME) in Japan
- Pivotal clinical data in Asian patients show a significant increase in mean visual acuity following treatment with Lucentis compared with laser therapy
- Diabetic macular edema is a leading cause of blindness in most developed countries in the working-age population

Basel, February 21, 2014 – Lucentis® (ranibizumab) has been approved by Japanese regulatory bodies for a fourth indication: the treatment of patients with diabetic macular edema (DME), a leading cause of vision loss among patients with diabetes. Laser therapy, the current standard of care in Japan, has provided stabilization of vision in many patients, but generally does not improve vision. Lucentis is the first licensed therapy to significantly improve vision in Asian patients with visual impairment due to DME.

“Lucentis has previously been shown to be an effective treatment, improving vision loss and vision-related quality of life for patients with DME,” said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. “Now Japanese patients living with DME have access to Lucentis, a drug with an unsurpassed efficacy and safety profile across multiple indications.”

Approval of Lucentis was based on results from the REVEAL trial, the first randomized clinical trial specifically designed to assess the efficacy and safety of Lucentis in Asian patients with visual impairment due to DME. In this Phase III trial, 396 patients from six countries, including Japan, were initially treated with monthly injections of 0.5 mg Lucentis, 0.5 mg Lucentis plus laser treatment or laser treatment alone for two months. Treatment was continued for twelve months if stable vision was not reached.

Efficacy and safety results from the REVEAL study were similar to other DME trials primarily conducted in Caucasians. At twelve months, REVEAL confirmed the superior efficacy of Lucentis with rapid and sustained visual acuity gains compared with laser therapy. Safety results showed that Lucentis was well tolerated in patients with DME both as monotherapy or when administered together with laser.

Diabetic macular edema is a consequence of diabetic retinopathy, the most common diabetic eye complication. DME is characterized by changes in the blood vessels of the retina, which is the light-sensitive layer at the back of the eye. In patients with DME, leakage from these abnormal blood vessels occurs in the central portion of the retina, called the macula. Because this part of the eye is responsible for sharp central vision, DME can lead to significant visual impairment. Visual impairment due to DME affects approximately 1–3% of patients with diabetes, and DME is a leading cause of blindness in the working-age population in most developed countries.
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 AMD, visual impairment due to DME and for visual impairment due to macular edema secondary to RVO, including both branch- and central-RVO. Also, Lucentis is licensed in more than 40 countries for the treatment of patients with visual impairment due to 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 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 2.2 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 “continued,” “commitment,” “breakthroughs,” “long-standing,” “can,” “goal,” or similar terms, or by express or implied discussions 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, unexpected regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including ongoing pricing pressures; general economic and industry conditions; the company’s ability to obtain or maintain proprietary intellectual property protection; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected 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, 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 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 136,000 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
1. Ohji M, et al. Efficacy and safety of ranibizumab 0.5 mg as monotherapy or adjunctive to laser versus laser monotherapy in Asian patients with visual impairment due to diabetic macular edema: 12-month results of the REVEAL study. ARVO 2012 Annual Meeting Abstracts.

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