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Investor News

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Bayer receives approval for Eylea® in China

Eylea® gains approval in China for the treatment of visual impairment due to neovascular (wet) age-related macular degeneration

Leverkusen, Germany, May 11, 2018 – Bayer announced today that Eylea® (aflibercept solution for injection into the eye) has been approved by the Chinese regulatory authorities for the treatment of visual impairment due to neovascular (wet) age-related macular degeneration (wAMD). This is the second indication for Eylea to be approved in China following its recent decision to approve the drug for treatment of visual impairment due to diabetic macular edema.

“Neovascular age-related macular degeneration is a rapidly progressive eye disease which can lead to permanent vision loss in just a few months if left untreated,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “We are delighted that with this approval, patients in China with this devastating disease will soon have access to a therapy that has been demonstrated in clinical trials and real world clinical settings to improve vision and long-term outcomes.”

Worldwide, AMD is estimated to cause blindness in three million people, accounting for 8.7% of all blindness and 50% of blindness in the developed world, with wAMD alone accounting for over 80% of legal blindness in all AMD patients. Without treatment, more than 80% of patients with wAMD would permanently lose some vision within two years and over three-quarters of these patients would be classified as legally blind at three years. The risk of AMD increases with age, and with the number of people over 65 years of age expected to more than double from 390 million to 800 million by 2025, the number of individuals affected by wAMD is also predicted to rise accordingly.

Data from the SIGHT Phase 3 clinical trial, along with results from VIEW 1 and VIEW 2 studies formed the basis of Bayer’s submission for Eylea in wAMD in China. The SIGHT

trial was conducted in China and demonstrated significant vision improvement in patients with wAMD when receiving Eylea. At 28 weeks, patients treated with Eylea gained an average of almost three lines compared to patients in the Photodynamic Therapy group who gained less than one line – measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart).

Eylea is a proven treatment option for patients with visual impairment due to wAMD and consistently delivers excellent outcomes to reduce preventable vision loss, both in randomised clinical studies as well as in real world clinical settings.

Outside of China Eylea has been approved in approximately 100 countries for five indications to treat patients with wAMD and patients with visual impairment due to: macula edema following retinal vein occlusion (RVO; branch RVO or central RVO) and diabetic macular edema (DME). Eylea has also been approved for the treatment of myopic choroidal neovascularization. Around 20 million vials of Eylea have been sold since launch worldwide resulting in an estimated number of almost 3 million patient years of experience.

Bayer and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of Eylea. Regeneron maintains exclusive rights to Eylea in the United States. Bayer has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of Eylea, except for Japan where Regeneron receives a percentage of net sales.

About neovascular age-related macular degeneration

Neovascular age-related macular degeneration (also known as wet AMD) is an eye disease that occurs when the structures in the back of the eye produce too much Vascular Endothelial Growth Factor (VEGF), a naturally-occurring protein which triggers the formation of new blood vessels. This excess VEGF causes the growth of abnormal new blood vessels under the macula – the part of the eye responsible for central vision – which can leak fluid into the eye and damage central vision, causing vision loss.

Wet AMD has far-reaching consequences on quality of life beyond the devastating sight loss it causes, and can lead to loss of independence, depression and social isolation. It requires early detection and regular, ongoing treatment with approved therapies to minimise and prevent central vision loss that can greatly impact patients' lives.

About the phase 3 SIGHT study

SIGHT is a 52-week, multicenter, double-masked, Phase 3 study in which Chinese patients with neovascular age-related macular degeneration (wAMD) were randomized to either receive 2 milligrams (mg) Eylea for injection every other month, following a loading phase of three consecutive doses per month, or photodynamic therapy (PDT). The primary endpoint for the study was the mean change in best corrected visual acuity (BCVA) from baseline to week 28, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standardized eye chart used in research to measure visual acuity. Other efficacy endpoints included the proportion of patients who lose less than 15 letters (confirmatory secondary endpoint) and mean change from baseline in central retinal thickness (CRT) at week 28 (exploratory endpoint).

Results from the primary and confirmatory secondary efficacy endpoints showed that Eylea treatment was clinically and statistically superior to PDT treatment at Week 28. At 28 weeks, patients treated with Eylea had a mean gain in BCVA of 14.0 letters compared to a gain of 3.9 letters in the group receiving PDT. Furthermore, nearly all patients (98.7%) treated with Eylea lost less than 15 letters vs. 92.1% of those treated with PDT. Patients who received Eylea also experienced a greater reduction in central retinal thickness (CRT) compared to PDT.

In the SIGHT study, Eylea was generally well tolerated and the safety profile was consistent with that observed in the previous VIEW trials. No new safety signals were identified in this study.

About VEGF and Eylea® (aflibercept solution for injection into the eye)

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. It is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema.

Eylea is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PGF) and thereby can inhibit the binding and activation of their cognate VEGF receptors.

About Bayer

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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