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Investor News

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Bayer receives first approval for Eylea® in China

Eylea is the first anti-VEGF drug approved in China for the treatment of visual impairment due to diabetic macular edema in patients with DME

Leverkusen, Germany, February 13, 2017 – Bayer announced today that Eylea® (aflibercept solution for injection into the eye) has been approved by the Chinese State Food and Drug Administration (CFDA) for the treatment of visual impairment due to diabetic macular edema (DME). This is the first indication for Eylea approved by the CFDA.

“With more than 110 million people in China suffering from diabetes, diabetic retinopathy coupled with DME is a serious complication that can threaten the vision of many working-age adults,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “The approval of Eylea in China in this important indication is great news for the increasing number of patients.”

Approximately one in three adults with diabetes worldwide – up to 93 million people – are affected by diabetic retinopathy (DR), a complication of diabetes which can lead to DME and blindness if left untreated. Without treatment, about half of patients with DME lose more than two lines of vision within two years of diagnosis, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, which can impact their ability to perform important daily activities such as working and driving. The results of three phase 3 studies – including more than 1200 patients – were very encouraging. The majority of patients with visual impairment due to DME experienced a significant, greater than two-line, improvement in visual acuity with aflibercept solution for injection, also approved under the brand name Eylea.

Outside of China Eylea has been approved in the majority of countries for five indications to treat patients with visual impairment due to: neovascular age-related macular degeneration (wet AMD) due to 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. Over 16 million doses of Eylea have been administered since launch worldwide.

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 Diabetic Macular Edema

Diabetic macular edema (DME) and diabetic retinopathy (DR) are common microvascular complications in people with diabetes. Diabetic retinopathy is a disease affecting the blood vessels of the retina. DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Visual impairment due to DME is estimated to affect 3-4% of people with diabetes and is therefore the most frequent cause of blindness in young and mid-aged adults in most developed countries. As the incidence of diabetes has been steadily climbing, experts from around the world expect that the number of people impacted by DME will also grow.

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 2016, the Group employed around 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. For more information, go to www.bayer.com.

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