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Investor News

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EYLEA® (aflibercept solution for injection into the eye):

Three-Year Results with EYLEA Show Sustained Improvement in Vision for People with Diabetic Macular Edema

Leverkusen, Germany, September 18, 2015 – Bayer HealthCare today announced new three-year results for the Phase 3 VIVID-DME trial of EYLEA® (aflibercept solution for injection) for the treatment of visual impairment due to diabetic macular edema (DME). The results, presented today at the 15th EURETINA Congress (17-20 September, 2015) in Nice, France, showed sustained improvements in best corrected visual acuity (BCVA) at three years, for EYLEA 2 milligrams (mg), compared to laser photocoagulation.

“Allowing people whose eye sight has been impaired as a result of their diabetes the opportunity to regain and retain their vision over time is critical,” said Prof. Jean-Francois Korobelnik, Principal Investigator of the VIVID-DME trial and Chief of Ophthalmology, CHU Bordeaux, who presented the data at the EURETINA Congress today. “Therefore these results are encouraging as the data show patients who achieved vision gains in the first year, maintained these gains over three years.”

The VIVID-DME trial is now complete. Patients in this study were randomized to receive either EYLEA 2 mg every month (n=136), EYLEA 2 mg every two months (after an initial injection every month for five consecutive doses) (n=135), or the comparator treatment of laser photocoagulation (n=132). After two years, patients randomized to laser could receive EYLEA 2 mg according to protocol specific re-treatment criteria (PRN).
After three years, patients receiving EYLEA every month had a mean gain in BCVA from baseline of 10.3 letters, patients receiving EYLEA every two months had a mean gain in BCVA from baseline of 11.7 letters. Patients in the laser photocoagulation treatment group had a mean change in BCVA from baseline of 1.6 letters. Additionally after three years, 41.2% of patients in the monthly group and 42.2% of patients receiving EYLEA 2 mg every two months maintained significant gains of at least 15 letters, or three lines,

as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standardized tool used in research to measure visual acuity, compared to 18.9% in the laser treatment group.

In this trial, patients treated with EYLEA show a similar overall incidence of adverse events (AEs) as compared to the laser treatment group. The safety results are in line with the 1 and 2 year data of the VIVID-DME and VISTA-DME trials as well as the known safety profile of EYLEA. AEs were typical of those seen in other studies in patients with diabetes receiving intravitreal anti-VEGF therapy. The most frequent ocular AEs observed in the EYLEA groups included conjunctival hemorrhage, cataract and increased intraocular pressure. The most frequent non-ocular AEs in these groups included nasopharyngitis and hypertension. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) occurred in 14 out of 136 patients (10.3%) receiving EYLEA every month, 6 out of 135 patients (4.4%) in the EYLEA every two months group and 7 out of 133 patients (5.3%) in the laser group.

EYLEA® is approved for the treatment of patients with neovascular age-related macular degeneration (wet AMD), visual impairment due to diabetic macular edema (DME) and macular edema secondary to central retinal vein occlusion (CRVO). In Europe, Japan and the U.S., EYLEA is approved for the treatment of visual impairment secondary to macular edema due to RVO (branch RVO or central RVO). In Japan EYLEA is additionally approved for the treatment of visual impairment due to myopic choroidal neovascularization. Over five million doses of EYLEA have been administered since launch worldwide.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare licensed the exclusive marketing rights outside the United States, where the companies share the profits equally 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. DR 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.

DME is the most frequent cause of blindness in young and mid-aged adults. Approximately 3% of people living with diabetes have visual impairment due to DME. As the incidence of diabetes has been steadily climbing, it is projected that the number of people impacted by DME will also grow.

About VEGF and EYLEA® (Aflibercept solution for injection)
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 (PlGF) and thereby can inhibit the binding and activation of their cognate VEGF receptors.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care and agriculture. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), is one of the world’s leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare’s aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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