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Investor News

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Bayer Receives Recommendation for Approval for New Treatment Option with Aflibercept Solution for Injection in EU

CHMP recommends EU approval for the treatment of visual impairment due to Macular Edema Secondary to Retinal Vein Occlusion

Leverkusen, January 23, 2015 – Bayer HealthCare today announced that aflibercept solution for injection into the eye has been recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for the treatment of patients with visual impairment due to macular edema secondary to retinal vein occlusion (RVO), which includes Macular Edema following Branch Retinal Vein Occlusion (BRVO) in addition to the previously-approved indication of Macular Edema secondary to Central Retinal Vein Occlusion (CRVO).

“Retinal vein occlusion is a common retinal vascular disorder with an estimated 16.4 million people affected worldwide, and it is a severe disease which is potentially blinding if not treated early and appropriately,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Vision impairment and blindness impact not only patients through loss of independence, but also their families. Therefore, we hope to be able to offer patients suffering from vision impairment secondary to BRVO and their physicians this new treatment option shortly.”

The positive CHMP recommendation is based on positive results from the double-masked, randomized, active-controlled phase 3 VIBRANT study in patients impacted by BRVO. The primary endpoint was the proportion of subjects who gained at least 15 letters in Best Corrected Visual Acuity (BCVA) from baseline at week 24, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity. More than half of the patients who were treated with aflibercept solution for injection gained at least three lines of vision.

The previously approved indication of Macular Edema secondary to CRVO was based on data from the Phase 3 COPERNICUS and GALILEO studies. In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 ETDRS letters of BCVA at 24 weeks compared to baseline on the ETDRS visual acuity charts.

About the Phase 3 VIBRANT Study

VIBRANT was a Phase 3, randomized, double-masked, active-controlled 52-week study, comparing aflibercept solution for injection 2 milligram (mg) monthly with laser photocoagulation in subjects with macular edema secondary to BRVO. At week 24, the primary endpoint of the study, 53% of patients who received aflibercept solution for injection 2 mg monthly gained at least 15 letters (equivalent to three lines) in best corrected visual acuity (BCVA) from baseline, compared to 27% of patients who received laser ($p<0.001$). In addition, aflibercept solution for injection met a key secondary endpoint, achieving a 17.0 letter mean improvement over baseline in BCVA compared to a 6.9 letter mean improvement in patients who received laser ($p<0.0001$).

Aflibercept solution for injection into the eye was generally well tolerated. Through week 24, the most common ocular adverse events in patients treated with aflibercept solution for injection were conjunctival hemorrhage and eye pain. The incidence of serious adverse events (SAE) was 9.9% in the aflibercept solution for injection group and 9.8% in the laser group. Up to week 24, one death and one Anti-Platelet Trialists' Collaboration (APTC) defined event (non-fatal stroke) occurred during the trial, both events occurred in patients in the laser group. There were no cases of intraocular inflammation. There was one ocular SAE in a patient in the aflibercept solution for injection group, which was a traumatic cataract.

About Retinal Vein Occlusion

Retinal Vein Occlusion (RVO) includes Branch Retinal Vein Occlusion (BRVO) and Central Retinal Vein Occlusion (CRVO). RVO has a significant global impact with an estimated 16.4 million people affected worldwide, including around 13.9 million with BRVO and 2.5 million with CRVO. RVO is the result of a blockage in a blood vessel of the retina, the light sensitive part of the eye responsible for seeing fine details. In CRVO, the blockage occurs in the main retinal vein at the optic nerve. In BRVO, the blockage occurs in one of the branches of the main retinal vein. If a blockage of retinal veins (central or branch) is not resolved, it can result in a number of complications: the most common reason for vision impairment in patients with RVO is macular edema, which describes swelling of the macula, which is the central portion of the retina.

About VEGF and 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.

Aflibercept solution for injection 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.

Aflibercept solution for injection into the eye has been approved under the brand name EYLEA® in more than 80 countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD) and around 60 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion. EYLEA is also approved for the treatment of diabetic macular edema (DME) in over 40 countries. Over three million doses of EYLEA have been administered since launch worldwide. In Japan, EYLEA has been additionally approved for the treatment of myopic choroidal neovascularization and an application for marketing authorization has also been submitted for the treatment of macular edema secondary to BRVO. In the U.S., EYLEA is already approved for the treatment of BRVO.

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

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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