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Investor News

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Bayer receives approval of new treatment regimen for Eylea® in the EU

- New treatment regimen could offer patients with neovascular age-related macular degeneration (AMD) extended proactive dosing already in the first year, while delivering strong visual gains
- Data from ALTAIR study demonstrate sustainability of new approach in 57% of patients who extended their treatment interval to 12 weeks or more

Berlin, August 1, 2018 – Bayer announced today that the European Commission has approved a new treatment approach for Eylea® to enable clinicians to combine proactive treatment with early extension of the injection interval for patients with neovascular age-related macular degeneration (nAMD). The new regimen allows clinicians already in the first year of treatment to extend patients' individual injection intervals based on visual and/or anatomic outcomes.

The new approach is based on results from the ALTAIR study, in which after 52 weeks 57% of patients had their next regularly scheduled Eylea injection at an interval of 12 weeks or more. Treatment intervals up to 16 weeks between injections have been studied. Patients participating in the study gained an average of up to 9.0 letters, including 50% of participants who gained 10 or more letters of vision at week 52, as measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart. These results were largely maintained during the second year, demonstrating the sustainability of this proactive approach.

"Neovascular age-related macular degeneration can have a devastating impact on a patient's life beyond the vision loss it causes," said Dr. Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG's Pharmaceuticals Division and Bayer Chief Medical Officer. "This new treatment regimen for Eylea has the potential to reduce the number of injections and clinic visits to less than four in the second year for certain

neovascular AMD patients, while still maintaining strong visual outcomes and the ability to see, this means that patients can spend more time doing what matters to them."

The updated product information brings forward a proactive 'Treat and Extend' (T&E) dosing regimen. This offers physicians the option already in the first year of EYLEA treatment to extend their patients' injection intervals by two- or four-weekly increments following initial dosing. If visual and/or anatomic outcomes deteriorate during the T&E dosing regimen, the treatment interval should be shortened accordingly. The initiation doses are three consecutive monthly doses, followed by one injection after two months.

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 neovascular AMD alone accounting for over 80% of legal blindness in all AMD patients. 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 neovascular AMD is also predicted to rise accordingly.

Eylea has been approved in the majority of countries for five indications to treat patients with: neovascular AMD (wet AMD), visual impairment due to diabetic macular edema (DME), retinal vein occlusion (RVO; branch RVO or central RVO) and myopic choroidal neovascularization. Eylea is the global market leader of anti-VEGF treatment, with estimated around 20 million doses administered worldwide since launch.

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 the ALTAIR study

The Phase IV ALTAIR study evaluated the efficacy and safety of Eylea using two T&E dosing regimens in Japanese patients with neovascular AMD. Patients taking part in the study received Eylea treatment for three consecutive monthly doses followed by an injection after two months (week 16 of the study). At week 16, patients were randomized 1:1 into two groups, in which the T&E dosing regimen was applied with either a 2-week (group 1) or a 4-week (group 2) adjustment of the treatment intervals. A total of 246 patients at 40 Japanese study sites aged on average 74 years participated in the trial.

Following a T&E dosing approach, treatment interval was defined by treating physicians based on the pre-defined criteria that considered imaging findings and changes in best-corrected visual acuity (BCVA). The interval between intravitreal aflibercept injections after the 16-week randomization visit could not be shorter than 8 weeks or longer than 16 weeks.

The primary endpoint in ALTAIR was change from baseline in BCVA as measured by ETDRS letter score at week 52. Other efficacy endpoints include the proportion of patients who maintain vision, proportion of patients who gain at least 15 letters of vision compared to baseline, mean change in Central Retinal Thickness (CRT) from baseline, and proportion of subjects without fluid on Optical Coherence Tomography (OCT) amongst others, at weeks 52 and 96 respectively. Treatment exposure-related parameters like number of injections and last treatment interval were also investigated.

Adverse event findings were consistent with the known safety profile for aflibercept and no major differences were observed between treatment arms during the first 52 weeks.

About neovascular AMD

Age-related macular degeneration (AMD) one of the leading causes of severe vision loss in older adults in the developed world, if left untreated. Macular degeneration is diagnosed as either dry (non-exudative) or neovascular (wet) age-related macular degeneration (exudative). It occurs when the structures in the back of the eye produce excess 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. Neovascular AMD can progress rapidly and if left untreated can lead to permanent vision loss in as little as three months.

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.

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 (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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