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Investor News

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New data for aflibercept show prolonged injection intervals

- Data from ALTAIR study demonstrate injection appointments at an interval of 12 weeks or more
- New data submitted to EMA to update the current product information

Leverkusen, Germany, February 12, 2018 – Bayer submitted new data to the European Medicines Agency (EMA) to update the current Eylea® (aflibercept injection into the eye) product information. The new data recommends extending the dosing interval during the first year of treatment. If approved, this alternative treatment option would give clinicians the opportunity to extend injection intervals with Eylea to 12 weeks and beyond, based on a patient's individual needs during the first year of treatment. Currently the Eylea product information recommends a dosing regimen once every two months in year one, following three initial consecutive monthly doses in patients with wet AMD (Age-related macular degeneration). The proposed label change is based on data from the recently presented ALTAIR trial, where at the end of the first year approximately 60% of patients on Eylea had their next scheduled appointment at an interval of 12 weeks or more.

"Based on the original pivotal studies with anti-VEGF therapy, patients with wet AMD would have required 12 visits to the clinic for either injections or monitoring in the first year of treatment," said Dr. Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG's Pharmaceuticals Division and Bayer Chief Medical Officer. "Having the additional opportunity to extend the injection intervals of Eylea to 12 weeks and beyond in the first year of treatment in a responsible and controlled manner could potentially result in as little as three to four visits to the clinic in the second year for some patients, whilst maintaining excellent visual outcomes and the ability to see."

The recently presented data from the ALTAIR T&E (Treat-and-Extend) Phase IV study adds further weight to the growing body of real world evidence data supporting the benefits of an early proactive regimen with Eylea.

Eylea has been approved in the majority of countries for five indications to treat patients with wet age-related macular degeneration (wet AMD), visual impairment 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. Eylea is the global market leader of anti-VEGF treatment, with over 16 million doses administered 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 the ALTAIR study

The Phase IV ALTAIR study evaluated the efficacy and safety of Eylea in Japanese patients with wet AMD, using two different T&E dosing regimens. Patients taking part in the study received Eylea treatment for three consecutive monthly doses followed by a single injection after two months at baseline. At week 16, patients were randomized 1:1 into two groups receiving treatment at four and two week interval extensions. A total of 255 patients aged ≥50 years at 40 Japanese study sites participated in the trial.

The treatment interval was defined by treating physicians based on the pre-defined criteria that considered imaging findings and changes in 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 best-corrected visual acuity (BCVA) as measured by Early Treatment Diabetic Retinopathy Study (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, at Week 52 respectively. Treatment exposure-related parameters like number of injections, last treatment interval were also investigated.

Adverse event findings are consistent with the known safety profile for aflibercept and no major differences were observed between treatment arms during the first 52 weeks. The study will continue until week 96.

At the one year time point of ALTAIR, approximately 60% of patients had their next scheduled injection appointment at an interval of 12 weeks or more. If maintained into year two this would mean that some patients would only need to receive three to four injections per year, which would mark a significant improvement on the current injection burden of anti-VEGF treatment.

About wet AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness, if left untreated. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

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 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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