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Investor News

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17th European Society of Retina Specialists (EURETINA) Congress

Bayer to showcase latest Ophthalmology research at EURETINA 2017

Leverkusen, Germany, August 30, 2017 – Bayer announced today that over 50 abstracts featuring the latest research from its worldwide market-leading anti-vascular endothelial growth factor (anti-VEGF) treatment EYLEA® (aflibercept solution for injection into the eye) will be presented at the upcoming European Society of Retina Specialists (EURETINA) Congress 2017.

Taking place between 7-10 September 2017 in Barcelona, Spain, seven oral presentations of data from Bayer-sponsored studies regarding aflibercept will showcase the company's commitment to addressing the treatment of a variety of life-altering conditions, such as wet age-related macular degeneration (wet AMD/nAMD), polypoidal choroidal vasculopathy (PCV, a variant of wet AMD), and the treatment of visual impairment due to diabetic macular edema (DME). Additionally, more than 40 abstracts from independent researchers demonstrate an increasingly high level of scientific interest in aflibercept and its potential benefits for patients across various indications.

In particular, data from the ALTAIR Treat and Extend study adds to the growing body of evidence supporting proactive use of this market-leading therapy.

The Phase IV ALTAIR clinical trial evaluated the efficacy and safety of aflibercept in Japanese patients with wet AMD, using two different approaches of a Treat and Extend (T&E) dosing regimen. Patients taking part in the study received one injection with aflibercept per month for three consecutive doses, followed by a further injection eight weeks later. At week 16, patients were randomized 1:1 into two groups receiving treatment at four and two week interval extensions. Within the T&E regimen after this time point, the minimum allowed dosing interval was 8 weeks and the maximum was

16 weeks. This dosing regimen in the first year is not approved outside of Japan. The primary endpoint was the mean change in best corrected visual acuity (BCVA) from baseline to Week 52.

The mean change in BCVA observed in the four weekly extension arm was shown to be non-inferior to that of the two weekly extension arm, with groups gaining 8.4 vs 9.0 letters respectively on an ETDRS chart – a tool used in research to measure visual acuity. This is equivalent to a gain of almost two lines on a snellen chart, the tool typically used during eye exams.

These new data from Japan have also shown the potential for extending treatment intervals with aflibercept, with a large proportion of patients in both treatment arms being assigned to an intended treatment interval of 12 weeks or beyond at the last visit; this was determined at the 52 week time point.

These findings reflect a stable anatomical and morphological status at the last regular evaluation of the patient, and mean that the investigators intended to treat 57% of patients with an interval of 12 weeks or beyond.

The incidence of ocular treatment-emergent adverse events (TEAEs) was similar between the four weekly extension and two weekly extension groups (15.4% vs 11.3%, respectively). The most common ocular TEAE was conjunctival haemorrhage (5.7% vs 2.4%, respectively).

A further phase IV study (ARIES) investigating a T&E dosing regimen with aflibercept is ongoing and could provide additional evidence of the extension of treatment intervals beyond eight weeks in year one, with first results expected to be available in 2018.

Bayer and independent researchers also announce findings from a number of real-world evidence (RWE) studies demonstrating the potential to achieve clinical trial-like results in routine clinical practice. Data presented will include results from the Bayer sponsored RAINBOW and PERSEUS studies, which assess the effectiveness of EYLEA observed in routine clinical practice in patients with wet AMD in France and Germany, respectively. These studies represent a significant landmark as the first to analyse the real world use of EYLEA in patients newly diagnosed with wet AMD in these countries.

Additionally, results from the PLANET study evaluating the efficacy and safety of EYLEA alone or in combination with rescue photodynamic therapy (PDT) in patients that have polypoidal choroidal vasculopathy (PCV) will be presented.

Bayer sponsored studies of note at EURETINA 2017 include the following:

- *Two different treat and extend dosing regimens for intravitreal aflibercept for wAMD: 52 weeks results of the ALTAIR study (ALTAIR)*
    - Oral Presentation, Room 117
    - Friday September 8th, 09:06 – 09:12

- *Impact of treatment interval in naïve nAMD patients: 12-month results of the PERSEUS and RAINBOW studies*
    - Oral Presentation, Room 118
    - Thursday September 7th, 08:54 – 09:00

- *Intravitreal aflibercept with and without photodynamic therapy in polypoidal choroidal vasculopathy: anatomical and morphological outcomes by optical coherence tomography in the PLANET study*
    - Oral Presentation, Room 117
    - Friday September 8th, 09:00 – 09:06

- *24-Month Outcomes of RAINBOW (Real-life use of intravitreal Aflibercept In FraNce: oBservatiOnal study in Wet age-related macular degeneration)*
    - Oral Presentation, Room 118
    - Thursday September 7th, 09:18 – 09:24

- *Efficacy comparison of anti-VEGF and laser photocoagulation in diabetic macular edema: a network meta-analysis incorporating individual patient-level data*
    - Oral Presentation, Room 114
    - Friday September 8th, 11:48 – 11:54

- *The impact of myopic macular degeneration on treatment outcomes of myopic choroidal neovascularisation with intravitreal aflibercept: Insights from the MYRROR study*
    - Oral Presentation, Room 114
    - Friday September 8th, 16:42 – 16:48

- *Intravitreal aflibercept in the treatment of polypoidal choroidal vasculopathy: the PLANET Study*
    - Oral Presentation, Room 111
    - Friday September 8th, 17:42 – 17:48

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.

Bayer AG and Regeneron Pharmaceuticals, Inc. are collaborating closely on the global development of EYLEA®. Regeneron has exclusive marketing rights for EYLEA® in the USA. Bayer AG has licensed the exclusive marketing rights outside the USA, where the companies share equally the profits from sales of EYLEA®, except for Japan where Regeneron receives a percentage on net sales. EYLEA is the global market leader of anti-VEGF treatment, with over 13 million treatments administered worldwide.

Bayer: Science For A Better Life
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 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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Forward-Looking Statements
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