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Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Bayer Receives Approval for EYLEA® in Japan for the Treatment of Macular Edema Secondary to Central Retinal Vein Occlusion

Leverkusen, Germany, November 22, 2013 – Bayer HealthCare has received approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for EYLEA® (aflibercept solution for injection) for the treatment of macular edema secondary to central retinal vein occlusion (CRVO).

“The additional approval of EYLEA in Japan for the treatment of macular edema secondary to CRVO is great news for patients in Japan suffering from this potentially sight-threatening eye condition,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The loss of vision not only impacts patients but also their families’ lives.”

VEGF Trap-Eye has been approved under the brand name EYLEA® in Europe, the United States, Japan, Australia, and in many other countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD). EYLEA has also been approved in Europe for the treatment of visual impairment due to macular edema secondary to CRVO as well as in the U.S. and in selected countries in Asia and Latin America for the treatment of macular edema following CRVO.

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 equally the profits from sales of EYLEA, except for Japan where Regeneron receives a royalty on net sales.

About Central Retinal Vein Occlusion (CRVO)

Over 66,000 people in major European countries, more than 100,000 people in the United States, and about 140,000 patients in Japan, over the age of 40 are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to an accumulation of deoxygenated blood and fluid in the retina. Macular edema secondary to CRVO causes retinal damage and loss of vision. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and macular edema. It has been shown that anti-VEGF treatment helps decrease vascular permeability and edema in the retina in patients with CRVO.

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. However, in certain diseases, it is associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema in certain diseases of the retina. Scarring and loss of fine-resolution central vision often results. In Central Retinal Vein Occlusion (CRVO), a blockage occurs in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels are elevated in response contributing to macular 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. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors.

About Regeneron Pharmaceuticals

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

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 18.6 billion (2012), 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Fabian Klingen (+49-214-30-35426)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Dr. Olaf Weber (+49-214-30-33567)

determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2012 and its Form 10-Q for the quarterly period ended September 30, 2013. The reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.