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Investor News

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Positive One Year results From Phase 3 Study in Central Retinal Vein Occlusion of VEGF Trap-Eye

Leverkusen, Germany, February 20, 2012 – Top-line results with VEGF Trap-Eye (aflibercept injection) after one year of treatment in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion (CRVO) confirm the primary endpoint results that were seen after 24 weeks from the two pivotal trials, GALILEO and COPERNICUS. The results are also in line with previously reported one-year results from the COPERNICUS study. These data are being presented at the World Ophthalmology Congress in Abu Dhabi today.

“The results of GALILEO and COPERNICUS are encouraging for patients with central retinal vein occlusion as they show a durable improvement in visual acuity after one year of treatment with VEGF Trap-Eye,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development.

Based on the results of these studies, Regeneron has already submitted a supplemental Biologics License Application (sBLA) in the U.S. and has been granted a FDA action date of September 23, 2012. Bayer HealthCare plans to file a marketing application with regulatory authorities in Europe in the second half of 2012. Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye.

The one-year GALILEO results showed that the proportion of subjects that gained at least 15 letters of vision from baseline to week 52 was 60.2% of patients receiving VEGF Trap-Eye, compared to 32.4% of patients receiving sham injections (exploratory tertiary endpoint; p=0.0004). In terms of gain in visual acuity from baseline until week 52, patients receiving VEGF Trap-Eye gained, on average, 16.9 letters of vision compared to a mean gain of 3.8 letters for patients receiving sham injections (exploratory tertiary endpoint; p<0.0001). The results achieved at week 52 corroborate the previously seen primary and secondary endpoints after 24 weeks, where 60.2 percent of patients

receiving monthly VEGF Trap-Eye 2 milligrams (mg) gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections (primary endpoint; p<0.0001), and patients receiving VEGF Trap-Eye had a mean gain of 18 letters compared to a mean gain of 3.3 letters for patients with sham injections (secondary endpoint; p<0.0001). Patients treated with VEGF Trap-Eye received an average of 2.5 VEGF Trap-Eye injections from week 24 to week 52. VEGF Trap-Eye was generally well tolerated. The most frequently reported ocular adverse events (≥ 10%) in the study eye in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, elevated intraocular pressure, macular edema, retinal hemorrhage, reduced visual acuity and retinal vascular disorder. The most frequently reported adverse events in the sham group (≥10%) were macular edema, retinal hemorrhage, retinal vascular disorder, eye irritation and reduction of visual acuity. 9.6% of patients in the VEGF Trap-Eye arm and 8.8% of patients in the sham arm presented with at least one ocular serious adverse event over the 52 weeks of the trial. The most frequently reported non-ocular adverse events (≥5%) in the VEGF Trap-Eye arm were back pain, bronchitis, nasopharyngitis, headache, and hypertension. The most frequently reported non-ocular adverse events (≥5%) in the sham group were fall, nasopharyngitis, headache, arthralgia, and hypertension.

The one-year COPERNICUS results showed that 55.3% of patients receiving VEGF Trap-Eye dosed monthly for 24 weeks, then on an as-needed (PRN) basis (guided by anatomic and visual acuity monitoring) over the next 28 weeks, gained at least 15 letters on an eye chart compared to 30.1% of patients who received sham injections for the first 24 weeks followed by VEGF Trap-Eye PRN from week 24 to week 52 (p=0.0006). Patients who went from monthly VEGF Trap-Eye dosing to PRN VEGF Trap-Eye dosing received a mean of 2.7 VEGF Trap-Eye injections, while patients who switched from sham to VEGF Trap-Eye PRN at week 24 received a mean of 3.9 VEGF Trap-Eye injections over 28 weeks. In terms of gain in visual acuity from baseline to week 52, patients receiving VEGF Trap-Eye gained, on average, 16.2 letters of vision compared to a mean gain of 3.8 letters for patients who switched from sham to VEGF Trap-Eye PRN (p<0.0001). At week 24, patients receiving VEGF Trap-Eye had a mean gain of 17.3 letters, while patients receiving sham had a mean loss of 4.0 letters (p<0.0001). VEGF Trap-Eye was generally well tolerated. The most frequently reported ocular adverse events (≥ 10%) in the study eye in the VEGF Trap-Eye arm were conjunctival hemorrhage, eye pain, maculopathy, elevated intraocular pressure, reduced visual acuity, and vascular disorder of the optic disc. The most frequently reported adverse events in the sham to VEGF Trap-Eye PRN arm (≥10%) were reduced visual acuity, conjunctival

hemorrhage, retinal hemorrhage, vitreous hemorrhage, and elevated intraocular pressure. At week 52, 5.3% of patients receiving VEGF Trap-Eye (monthly to PRN) and 16.2% of patients (sham to VEGF Trap-Eye PRN) reported at least one ocular serious adverse event. The most frequently reported non-ocular adverse events (≥5%) in the VEGF Trap-Eye arm were nasopharyngitis, sinusitis, bronchitis, influenza, and hypertension. The most frequently reported non-ocular adverse events (≥5%) in the sham to VEGF Trap-Eye PRN arm were nasopharyngitis, present protein in urine, increased urine protein/creatinine ratio, increased blood glucose, and hypertension.

About the Phase 3 CRVO Program

Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the almost identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies received six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections.

Patients in both trials were randomized in a 3:2 ratio with 114 patients receiving VEGF Trap-Eye and 74 randomized to the control arm in COPERNICUS and 104 patients randomized and treated with VEGF Trap-Eye and 68 randomized and treated in the control arm in GALILEO. At the end of the initial six months, all patients randomized to VEGF Trap-Eye were dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months were eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients were eligible for rescue laser treatment. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

About Central Retinal Vein Occlusion (CRVO)

Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help

decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About VEGF Trap-Eye

VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally the profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products in the United States, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA® (aflibercept) Injection, and has filed regulatory applications with the U.S. Food and Drug Administration (FDA) for second indications for each of these products. A regulatory application has also been submitted to FDA for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Phase 3 studies are in progress with EYLEA® in a third indication, with ZALTRAP® in a second indication, and with product candidate Sarilumab. Earlier-stage clinical programs are underway with nine additional product candidates. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at www.regeneron.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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Regeneron Forward Looking Statement

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of EYLEA and ARCALYST and Regeneron's product candidates, potential new indications for marketed products, and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other product and drug candidates and possible new indications for marketed products, competing drugs that may be superior to EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products, uncertainty of market acceptance of EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products, unforeseen safety issues resulting from the administration of products and product candidates in patients, unanticipated expenses, the availability and cost of capital, 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 canceled or terminated without any 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, 2010 and Form 10-Q for the quarter ended September 30, 2011. 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, unless required by law.

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.