News Release

Bayer Yakuhin, Ltd.
Santen Pharmaceutical Co., Ltd.

Intravitreal VEGF Inhibitor "EYLEA® Solution for Intravitreal Injection" and "EYLEA® Intravitreal Injection KIT" Approved for the Treatment of Wet Age-Related Macular Degeneration in Japan

Osaka, September 28, 2012 - Bayer Yakuhin, Ltd. (Osaka, hereafter Bayer Yakuhin) and Santen Pharmaceutical Co., Ltd. (Osaka, hereafter Santen) announced today that Bayer Yakuhin has received the marketing authorization for the new drug application for the intravitreal VEGF* inhibitor EYLEA® solution for intravitreal injection 40 mg/mL and EYLEA® intravitreal injection KIT 40 mg/mL (aflibercept [recombinant], hereafter EYLEA) for the treatment of patients with age-related macular degeneration with subfoveal choroidal neovascularization (wet age-related macular degeneration). The launch is subsequently planned after inclusion in the National Health Insurance (NHI) reimbursement price list.

* VEGF = vascular endothelial growth factor

EYLEA, also known as VEGF Trap-Eye, is a novel intravitreal VEGF inhibitor co-developed by Bayer HealthCare in Germany and Regeneron Pharmaceuticals, Inc., in the United States for the treatment of retinal disorders. It is a recombinant fusion protein consisting of portions of extracellular domains of human VEGF receptors 1 and 2 fused to the Fc portion of human IgG1 and formulated as an isosmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor to which VEGF-A and placental growth factor (PlGF) bind with affinity greater than that for their natural receptors and thus can inhibit the binding and activation of these cognate VEGF receptors. Eylea thus inhibit abnormal vascularization.

The approved regimen is "2 mg of Aflibercept (Genetical Recombination) (0.05 mL) is administered by intravitreal injection once every month for three times consecutively (initiation phase). In the following maintenance phase, usually, it is administered by intravitreal injection

once every 2 months. The dosing interval may be adjusted according to the patient's symptom/condition." The regimen was set based on the results of 2 global Phase III studies VIEW 1 and VIEW 2. Initial 3 monthly administrations in the loading phase followed by the proactive treatment/scheduled doses every other month in the maintenance phase is expected to improve and maintain visual acuity.

Dr. Yuichiro Ogura, Professor of Ophthalmology and Visual Science at Nagoya City University Graduate School of Medical Sciences and Medical School and a member of the steering committee of the global Phase III clinical study VIEW 2 said, "The number of patients with wet age-related macular degeneration (wet AMD) is increasing in Japan. The introduction of EYLEA will be advantageous for wet AMD patients because it will increase the therapeutic options, because EYLEA regimen dosed once in two months demonstrated equivalent efficacy compared with the monthly ranibizumab regimen in the clinical trials."

EYLEA was approved in in the United States in November 2011 and in Australia earlier this year for the treatment of wet AMD. EYLEA recently received a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency.

In Japan, Bayer Yakuhin holds the marketing authorization approved by the MHLW, and Santen will distribute the product according to the co-promotion agreement concluded with Bayer Yakuhin on May 7, 2012. Bayer Yakuhin and Santen will both provide drug information to healthcare professionals.

<Overview of EYLEA>

Product name	EYLEA® solution for intravitreal injection 40 mg/mL EYLEA® intravitreal injection KIT 40 mg/mL
Non-proprietary name	Aflibercept (recombinant)
Indication	Age-related macular degeneration with subfoveal choroidal neovascularization
Regimen	2 mg of Aflibercept (Genetical Recombination) (0.05 mL) is administered by intravitreal injection once every month for three times consecutively (initiation phase). In the following maintenance phase, usually, it is administered by intravitreal injection once every 2 months. The dosing interval may be adjusted according to the patient's symptom/condition

Date of marketing authorization	September 28, 2012

About VIEW 1 and VIEW 2

Two global Phase III clinical studies (VIEW 1 and VIEW 2) were conducted targeting wet AMD patients. In these trials, it was demonstrated that aflibercept 2mg dosed every other month (following 3 initial monthly injections) successfully met the primary endpoint of statistical non-inferiority, compared to ranibizumab 0.5 mg dosed every month, in the proportion of patients who maintained or improved vision (less than 15 letters of vision loss on an ETDRS chart) over 52 weeks. The most common adverse reactions reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain and increased intravitreal pressure.

About VEGF

Vascular endothelial growth factor (VEGF) is a natural protein in the body. It stimulates the formation of new blood vessels (neovascularization) to support tissue and organ growth. At the same time, it is also involved in abnormal angiogenesis in the eye in patients with certain disorders such as wet AMD, and induces edema by increasing vascular permeability.

About Wet AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness. AMD 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 severe visual dysfunction 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. In Japan, wet AMD is the fourth most common cause of acquired blindness[1], and the number of patients is increasing. The research conducted in 2007 targeting residents in Hisayama, Fukuoka, showed that 1.2% of residents over the age of 50 had wet AMD in at least one eye[2]. Extrapolating from this study, the number of patients in Japan estimated to have wet AMD eligible for treatment with anti-VEGF therapy is approximately 700,000.

References:

1 Ophthalmic Epidemiology, 17(I), 50-57, 2010: “Prevalence of Visual Impairment in the Adult Japanese Population by Cause and Severity and Future Projections” Masakazu Yamada, Yoshimune Hiratsuka, Chris B. Roberts, M. Lynne Pezzullo, Katie Yates, Shigeru Takano, Kensaku Miyake, and Hugh R. Taylor

2 New Ophthalmology 26(1) 25-30, 2009: Observational study (cohort study): Hisayama-cho study. Yasuda M.

About Santen

Founded in 1890, Santen is a global company headquartered in Osaka, Japan. Santen researches, develops and markets ophthalmic products for physicians worldwide. Among prescription ophthalmic pharmaceuticals, Santen holds the top share within the Japanese market and is one of the leading ophthalmic companies worldwide. For more information, visit
http://www.santen.co.jp/

About Bayer Yakuhin, Ltd.

Bayer Yakuhin Ltd., headquartered in Osaka, is a healthcare company which combines business activities of Pharmaceuticals, Radiology & Interventional and Animal Health (companion and food animal products). Pharmaceuticals business is focused on the following areas: Cardiovascular & Neurology, Oncology & Hematology, Women's Health & Dermatology and Ophthalmology.Bayer Yakuhin aims to be one of leading pharmaceutical companies, which responds to Japanese patients' unmet medical needs, with the spirit of Bayer's corporate slogan "Science For A Better Life".
Bayer Yakuhin homepage: http://www.bayer.co.jp/byl

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 17.2 billion (2011), 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 55,700 employees
(Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

To learn more about age-related macular degeneration (AMD), please visit:
www.bayerpharma.de/en/AMD

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 three products in the United States, EYLEA® (aflibercept) Injection, ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, and ARCALYST® (rilonacept) Injection for Subcutaneous Use; ZALTRAP is co-commercialized with Sanofi. Regeneron has filed a regulatory application with the U.S. Food and Drug Administration (FDA) for a second indication for EYLEA. Phase 3 studies are in progress with EYLEA in two additional indications and with product candidates sarilumab and REGN727. 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.

Bayer 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.

Santen Forward-looking Statements

Information provided in this press release contains so-called "Forward-looking Statements". The realizations of these forecasts are subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial condition are subject to the effects of change in regulations made by the governments of in Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.