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SANTEN ANNOUNCES THE INITIATION OF A MULTINATIONAL PHASE III PROGRAM EVALUATING SIROLIMUS (DE-109) FOR THE TREATMENT OF NON INFECTIOUS POSTERIOR UVEITIS

NAPA, CA (JUNE 20, 2011) -- Santen Inc., the U.S. subsidiary of global ophthalmic pharmaceutical company Santen Pharmaceutical Co., Ltd. (Osaka, Japan) today announced the initiation of a global Phase III clinical study evaluating its investigational drug sirolimus (DE-109) for the treatment of non infectious posterior uveitis.

Sirolimus, originally known as rapamycin, is a highly potent, broad-acting compound that has been demonstrated to combat disease through multiple mechanisms of action. It is known to be an immunosuppressive and anti-proliferative agent in humans and an anti-angiogenic, anti-migratory, anti-fibrotic, and anti-permeability agent in animal models.

The Phase III study, SAKURA (Study Assessing double-masKed Uveitis tReAtment), opened enrollment in May. It is a multinational, multicenter, randomized, double-masked study assessing the safety and efficacy of three different doses of sirolimus. The doses will be administered every two months in subjects with active, non-infectious uveitis of the posterior segment of the eye. Approximately 500 subjects with active, non-infectious posterior, intermediate or panuveitis will be enrolled at approximately 150 sites. Eligible subjects will be randomized into three arms each receiving different doses of DE-109 by intravitreal injection. The primary endpoint, the proportion of subjects with a vitreous haze score of zero (Standardized Uveitis Nomenclature [SUN] Photographic scale) will be assessed at month five and subjects will be followed for an additional seven months for safety evaluation.

“We are thrilled about the initiation of the SAKURA study, as the biggest thing that the program addresses is a major unmet need in the posterior uveitis space,” said Naveed Shams, M.D. Ph.D, Head of Global Clinical Development and Medical Affairs in the Santen Global Research & Development Division. “If proven to be clinically effective, it should significantly impact the quality of life of patients with non-infectious, posterior uveitis. Intravitreal sirolimus is expected to significantly

reduce the use of systemic and local corticosteroids to treat non-infectious posterior uveitis and hence reduce the incidence of corticosteroid-induced co-morbidities.”

Initiation of the SAKURA study is in line with Santen’s desire to expand its presence worldwide and to develop and market innovative new products that address unmet medical needs in the dry eye, vitreo-retinal and glaucoma therapeutic segments.

ABOUT SIROLIMUS

Sirolimus was isolated in the 1970’s from *Streptomyces hygroscopicus* in soil samples from Easter Island. Sirolimus is the active pharmaceutical ingredient in 2 products approved by the FDA, specifically Rapamune®, an immunosuppressive agent used in renal transplant patients, and the CYPHER® Sirolimus-eluting Coronary Stent approved for improving coronary luminal diameter in patients with symptomatic ischemic disease.

ABOUT UVEITIS

Uveitis is a group of intraocular inflammatory disorders with both infectious and autoimmune etiologies. Typically uveitis is classified by anatomic location in the uvea. Anterior uveitis is the most common type and can involve the cornea, iris, and/or ciliary body. Intermediate uveitis affects the middle portion of the eye, such as the ciliary body and vitreous. Posterior uveitis can involve the vitreous, choroid, retina, and/or optic nerve. Panuveitis, also referred to as diffuse, can encompass anterior, intermediate, and posterior segments. Uveitis is responsible for approximately 10% of the visual handicap in Western countries.

ABOUT SANTEN INC.

Santen Inc., currently based in Napa, California, is the U.S. subsidiary of Santen Pharmaceutical Co., Ltd., a billion-dollar global company headquartered in Osaka, Japan since 1890. Recently, the company announced that its U.S. corporate headquarters will relocate to Emeryville, California in early July 2011 in preparation for substantial expansion of the organization.

Santen researches, develops and markets ophthalmic products for physicians worldwide. Santen has subsidiaries in the U.S., Europe and Asia, including its wholly-owned California-based Santen Inc. Santen Inc. also maintains a satellite business development office in Irvine, California which provides direct access to the regional cluster of ophthalmic companies operating in that area. Among prescription ophthalmic pharmaceuticals, Santen holds the top share within the Japanese and Chinese markets and is one of the leading ophthalmic companies worldwide. Santen’s global product pipeline includes a number of prescription pharmaceuticals in varying clinical trial phases. A detailed listing, as well as additional corporate information, is available online at www.santeninc.com.