



FOR IMMEDIATE RELEASE

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SANTEN ANNOUNCES EMA ORPHAN DRUG STATUS FOR SIROLIMUS (DE-109)

Emeryville, CA (Sept 8, 2011) -- Santen Inc., the U.S. subsidiary of global ophthalmic pharmaceutical company Santen Pharmaceutical Co., Ltd. (Osaka, Japan) today announced the European Commission (EC) has granted orphan drug status for sirolimus (DE-109) for the treatment of chronic non-infectious uveitis. The designation follows a positive opinion from the Committee for Orphan Medicinal Products (COMP) within the European Medicines Agency (EMA) in June. Orphan designation will be published on the EMA website.

ABOUT EUROPEAN ORPHAN DRUG DESIGNATION

European Orphan Drug designation by the European Commission is granted to medicines intended for treatment of life-threatening or chronically debilitating pathologies that affect no more than 5 in 10,000 people in the European Union (EU). An orphan designation in the EU confers a range of benefits to sponsor companies including scientific advice on all aspects of product development at a reduced fee, direct access to the centralized procedure for marketing authorization, and eligibility for certain financial incentives made available by the Community and by the Member States to support research into and development of orphan drugs. If the product is approved for marketing, the designation also provides 10 years of marketing exclusivity subsequent to product approval if the orphan designation still prevails at the time of marketing authorization.

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 EMA and the US Food and Drug Administration (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.

Sirolimus, originally known as rapamycin, is a broad-acting compound that is known to be an immunosuppressive and anti-proliferative agent. It is currently being evaluated in a Phase III

study entitled SAKURA (Study Assessing double-masKed Uveitis tReAtment), to assess the safety and efficacy of different doses of sirolimus.

As Sirolimus is currently being evaluated in a Phase III clinical trial, Santen Inc. does not make any safety or efficacy claims about Sirolimus as a treatment for uveitis. The content of this Press Release is for informational purposes only.

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., based in Emeryville, 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 its relocation of the U.S. corporate headquarters from Napa to Emeryville, California in preparation for substantial expansion of the organization as well as the creation of the new Global Clinical Development and Medical Affairs Department which will be responsible for all global clinical projects.

Santen researches, develops and markets ophthalmic products 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.

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