



FOR IMMEDIATE RELEASE

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

Emeryville, CA (Nov 10, 2011) – Santen Inc., the U.S. subsidiary of global ophthalmic pharmaceutical company Santen Pharmaceutical Co., Ltd. (Osaka, Japan), & Global Clinical Development and Medical Affairs at Santen today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for sirolimus (DE-109) for the treatment of chronic/refractory anterior non-infectious uveitis, non-infectious intermediate uveitis, non-infectious panuveitis, and non-infectious uveitis affecting the posterior segment of the eye. The designation follows the granting of orphan drug status by the European Commission in September 2011. "This is an important milestone in the development of sirolimus for non-infectious uveitis affecting the posterior segment of the eye," said Toshiaki Nishihata, Ph.D., Director, Executive Corporate Officer U.S. and Europe Business, and Head of Research and Development Division at Santen Inc.

ABOUT FDA ORPHAN DRUG DESIGNATION

The mission of the FDA Office of Orphan Products Development (OOPD) is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. The program has successfully enabled the development and marketing of more than 350 drugs and biologic products for rare diseases since 1983. In contrast, the decade prior to 1983 saw fewer than 10 such products come to market.

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 two products approved by the European Medicines Agency (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 in non-infectious posterior uveitis.

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, with 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 various clinical trial phases. A detailed listing, as well as additional corporate information, is available online at www.santeninc.com.

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