News Release

SANTEN PHASE III STUDY MEETS PRIMARY ENDPOINT FOR THE TREATMENT OF NON-INFECTIOUS POSTERIOR SEGMENT UVEITIS (NI-PSU)

Emeryville, CA (April 4, 2014) -- Santen Inc., the U.S. subsidiary of global ophthalmic pharmaceutical company Santen Pharmaceutical Co., Ltd. (Osaka, Japan) today announced that SAKURA (Study Assessing double-masKed Uveitis tReAtment) Study 1, the first of two Global Phase III studies evaluating intravitreal injections of sirolimus in patients with non-infectious posterior segment uveitis (NI-PSU), met its primary endpoint.

"NI-PSU is a debilitating disease which affects working-aged adults worldwide. Currently, there are no FDA approved non-steroidal treatments for this sight threatening condition. We are excited by the SAKURA data and believe sirolimus may provide physicians with the first non-steroidal intravitreal treatment option for their patients suffering with NI-PSU" said Dr. Naveed Shams, Chief Scientific Officer and President & CEO of Santen Inc.

SAKURA is an ongoing multinational, multicenter, randomized, double-masked study assessing the safety and efficacy of sirolimus. 347 patients with non-infectious posterior, intermediate or panuveitis were enrolled at approximately 150 sites for SAKURA Study 1. Eligible patients were randomized into three treatment arms, each receiving different doses of sirolimus by intravitreal injection. The primary endpoint was the proportion of patients achieving a vitreous haze score of zero at month five (Standardized Uveitis Nomenclature [SUN] Photographic scale). SAKURA Study 2 continues to enroll patients under the same protocol.

ABOUT SIROLIMUS

Sirolimus is a mTOR inhibitor, an immunomodulator, which is the same active pharmaceutical ingredient in two FDA approved products; Rapamune®, an immunosuppressive agent used in renal transplant patients, and CYPHER® (Sirolimus-eluting Coronary Stent), approved for improving coronary luminal diameter in patients with symptomatic ischemic disease. Intravitreal sirolimus is a proprietary ocular formulation of sirolimus.

ABOUT UVEITIS

Uveitis is an intraocular inflammatory condition which may or may not have an infectious component and is often classified by anatomic location in the eye. NI-PSU

includes intermediate uveitis which can affect the ciliary body and vitreous; posterior uveitis which can involve the vitreous, choroid, retina, and/or optic nerve; and panuveitis which encompasses anterior, intermediate and posterior segments. Currently, steroids and systemic immunosuppressants are frequently used to reduce the inflammation in the eye and can be associated with significant morbidity.

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