

EUROPEAN MEDICINES AGENCY ACCEPTS SANTEN'S MARKETING APPLICATION FILING FOR INTRAVITREAL SIROLIMUS FOR THE TREATMENT OF NONINFECTIOUS UVEITIS OF THE POSTERIOR SEGMENT

March 2, 2015 -- Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) announced that the European Medicines Agency (EMA) has accepted the company's Marketing Authorization Application (MAA) filing for the use of intravitreal sirolimus, an investigational mTOR inhibitor, for the treatment of noninfectious uveitis (NIU) of the posterior segment. The MAA filing marks the beginning of a regulatory review process for intravitreal sirolimus, which has the potential to address an unmet need in the European Union (EU) where NIU of the posterior segment is a leading cause of blindness¹.

"Given the risks associated with currently available therapeutic options for NIU of the posterior segment, a chronic inflammatory condition in many cases, there is a significant need for novel treatments that could be used in a sustained manner to optimize clinical outcomes," says Dr. Naveed Shams, Chief Scientific Officer and Head, Global R&D, Santen Ltd. "If approved, intravitreal sirolimus would represent a significant step forward in the management of NIU of the posterior segment of the eye."

The EMA submission is supported by data from SAKURA (Study Assessing double-masKed Uveitis tReAtment), a pivotal Phase 3 study. The submission seeks approval to market the sirolimus, 440 ug dose for the chronic treatment of NIU of the posterior segment of the eye. Key outcomes supporting the indication include data on proportion of subjects achieving a vitreous haze score of 0 at Month 5, proportion of subjects achieving a vitreous haze score of 0 or 0.5+ at month 5, the proportion of subjects achieving an improvement in vitreous haze score of 2 units, and proportion of subjects successfully tapering-off systemic corticosteroids at Month 5.

ABOUT SIROLIMUS

Intravitreal sirolimus, a first-in-class local immunoregulatory therapy, being evaluated for the treatment of NIU of the posterior segment, inhibits mTOR, which plays a critical role in stimulating T-cell proliferation leading to the release of proinflammatory cytokines. By inhibiting mTOR, sirolimus interrupts a critical pathway that perpetuates the inflammatory process, controlling the disease's progression. Intravitreal sirolimus is a proprietary ocular formulation of sirolimus currently under review by the EMA.

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. NIU of the posterior segment 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 and posterior segments of the eye. While currently available treatments, such as systemic corticosteroids and immunomodulatory therapies, are effective in treating inflammation in the eye, they are associated with a range of serious adverse effects that may limit the ability to achieve long-term therapeutic success.

ABOUT SANTEN

As a specialty company dedicated to the ophthalmic and anti-rheumatic fields, Santen carries out the research, development, sales, and marketing of pharmaceuticals. The company has 15 bases in 12 countries globally and delivers products to consumers in more than 70 countries. In Japan, Santen holds the No. 1 share in the prescription ophthalmic pharmaceutical market. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs.

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 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.

This press release is also prepared in other languages. However this English document is the original document, and documents prepared in other languages are for your reference only. In case of any discrepancy between the English and translated versions, the English version will prevail. Please refer to <http://www.santen.com> for the original English document

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References:

1. Wakefield D, Chang JH. Epidemiology of uveitis. *Int Ophthalmol Clin*. 2005;45(2):1-13.