## Agreement Concerning CS-011 as Dry Eye Drug Candidate

September 26, 2005 – Sankyo Co., Ltd. (headquartered Tokyo, Japan. President: Takashi Shoda) and Santen Pharmaceutical Co., Ltd. (headquartered Osaka, Japan. President: Takakazu Morita) today announced that they entered into an agreement concerning the worldwide exclusive development, manufacturing and marketing rights for CS-011 (rivoglitazone) as an ophthalmic treatment for corneal and conjunctival epithelial disorders, including dry eye. The compound is currently under development by Sankyo as an anti-diabetic.

Under the agreement, Sankyo will manufacture and supply the bulk material, and Santen will develop, manufacture and market the product as the corneal and conjunctival epithelial disorder treatment, including dry eye. Sankyo has the option to co-promote the product in Japan.

The estimated number of dry eye patients is 8 million within Japan, and is expected to grow due to the increase of computer use and the aging population. Dry eye syndrome causes not only dehydration but also inflicts wounds on the ocular surface. Treating this disorder is becoming increasingly important, and there are still unmet medical needs in this area, especially for severe cases.

CS-011 is currently in Phase 2b clinical trials in the United States as an anti-diabetic. Santen has demonstrated the compound's potent therapeutic effects on corneal and conjunctival epithelial disorders, including dry eye. CS-011 has an action mechanism which differs from any other existing treatment or drug candidate in development. It is expected to show a potent effect on corneal and conjunctival epithelial disorders by directly acting on the corneal and conjunctival epithelial cells.

Through this agreement, Sankyo strives to optimize the product value of CS-011 by licensing with Santen. Santen is Japan's top prescription ophthalmic manufacturer and one of the world's leading ophthalmic companies, and has excellent development and marketing capabilities.

In addition to marketing the corneal and conjunctival epithelial disorder treatment HYALEIN®, Santen currently has development projects for this therapeutic area. CS-011 will add to Santen's domestic product pipeline as well as further strengthening its global competitiveness.

This agreement is the second between Sankyo and Santen, following the glaucoma treatment candidate CS-088 (development code: DE-092. Generic name: olmesartan. Current stage: Phase 2 clinical trials) which was licensed in March 2002. The two companies will work together for these categories in order to offer more detailed therapeutic options tailored to each patient's condition and to improve the quality of life of as many patients as possible.

## [For Reference]

**Dry eye**: corneal and conjunctival epithelial disorder that results from quantitative or qualitative abnormality of tears caused by decreased tear secretion, autoimmune diseases or other causes.

## **Mechanism of Dry Eye Development**

