News Release

Santen Announces Preliminary Results of Overseas Clinical Trials of Two Glaucoma Drug Candidates

February 14, 2006, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (President: Takakazu Morita) announced preliminary results of the overseas clinical trials of two drug candidates for lowering intraocular pressure in glaucoma and ocular hypertension: an angiotensin II receptor antagonist, DE-092 (INN: Olmesartan) , and a prostaglandin derivative, DE-085 (INN: Tafluprost).

- **DE-092 (INN: Olmesartan)**

  Santen has conducted an early Phase II clinical study of DE-092 in the United States through its wholly-owned subsidiary, Santen Incorporated, based in Napa, California, U.S.A. The U.S. study aimed to explore DE-092's IOP-lowering effect, and the dose-response relationship between several concentrations of DE-092. Although data analysis indicated some IOP reduction for DE-092, the efficacy was insufficient, and no clear dose-response relationship was seen among the DE-092 concentrations. Therefore, Santen plans to consider development options such as conducting another dose-response study, and re-positioning of DE-092 in the U.S. and Europe after the Japanese Phase II results are available.

  In Japan, DE-092 demonstrated a certain IOP-lowering effect in an early Phase II study, and Santen is currently conducting a late Phase II study as originally planned.

- **DE-085 (INN: Tafluprost)**

  Santen is conducting several DE-085 comparison studies in the U.S. and Europe. Through its wholly-owned subsidiary, Santen Oy, based in Tampere, Finland, Santen has conducted a European Phase III trial which was designed to confirm DE-085's non-inferiority to latanoprost ophthalmic solution 0.005% (latanoprost). The data analysis demonstrated DE-085's strong IOP-lowering effect as expected for prostaglandins, but the drug did not demonstrate non-inferiority to latanoprost for the primary endpoint. However, this study is ongoing, and Santen will conduct a detailed analysis once final study results are available. Santen will review the development plan for DE-085 in the U.S. and Europe after completing a comprehensive statistical analysis of data from another comparison study versus timolol maleate ophthalmic solution 0.5% (timolol) which is currently ongoing in the U.S and Europe. In Japan, Santen has conducted several Phase III studies including a comparison study with latanoprost which demonstrated DE-085's non-inferiority to latanoprost. The remaining studies are on schedule and progress towards a Japanese NDA filing is continuing as planned.

  Santen will announce its future overseas development plans for these two product candidates when a decision is made.

[For reference]

DE-092 (INN: Olmesartan)

DE-092 is a drug candidate developed by Sankyo Co., Ltd., Tokyo, a wholly-owned subsidiary of Daiichi Sankyo Co., Ltd., under the development code CS-088. Santen acquired the global development, manufacturing and marketing rights to the ophthalmic form of olmesartan through an agreement with Sankyo in March 2002 and is currently conducting clinical development.

DE-085 (INN: Tafluprost)

DE-085 is a novel prostaglandin drug candidate being studied for the reduction of intraocular pressure in primary open angle glaucoma and ocular hypertension. DE-085 is under co-development by Santen and Asahi Glass Co., Ltd., Tokyo. Santen is conducting pharmaceutical and clinical development, while Asahi Glass is responsible for manufacturing development of the active pharmaceutical ingredient.

Angiotensin II receptor antagonist

Angiotensin II is a protein which causes an increase in blood pressure by constricting blood vessels. Angiotensin II receptor antagonists control blood pressure by acting on the angiotensin II receptor.

Prostaglandin

Prostaglandin is one of a number of physiologically active substances that participate in a wide range of body functions such as the dilation of blood vessels, control of blood pressure, and dilation of respiratory system.

Latanoprost ophthalmic solution 0.005% (latanoprost)

Latanoprost is a prostaglandin drug for the reduction of intraocular pressure in open angle glaucoma and ocular hypertension.

Timolol maleate ophthalmic solution 0.5% (timolol)

Timolol is a beta-blocker drug for the reduction of intraocular pressure in open angle glaucoma and ocular hypertension.

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