

Santen Announces Approval of Alesion® 0.05% Ophthalmic Solution for Allergic conjunctivitis Treatment in Japan

September 20, 2013, Osaka, Japan-- Santen Pharmaceutical Co., Ltd. announces to receive approval from the Japan Ministry of Health, Labor and Welfare (MHLW) for the manufacture and sales of Alesion® 0.05% Ophthalmic Solution (generic name: epinastine HCl), a topical anti-allergic agent.

Santen obtained the rights from Nippon Boehringer Ingelheim Co., Ltd. (Tokyo) to develop Alesion® 0.05% Ophthalmic Solution in Japan as an effective treatment for allergic conjunctivitis. Japanese clinical trials have revealed that epinastine HCl, the active ingredient in Alesion® 0.05% Ophthalmic Solution, blocks histamine H₁ receptors and inhibits the release of chemical mediators from mast cells, which in turn alleviates ocular itching and hyperemia, the main symptoms of allergic conjunctivitis. No ocular or systemic serious adverse drug reactions were observed in these clinical studies.

This approval of Alesion® 0.05% Ophthalmic Solution will benefit Santen's efforts to improve the quality of life of patients by giving health care professionals a wider range of treatment options.

<Product Outline>

Product Name:	Alesion® 0.05% Ophthalmic Solution
Generic name:	Epinastine HCl
Formulation:	Aqueous ophthalmic solution
Indication:	Allergic conjunctivitis
Dosage:	One drop at a time, four times daily in the morning, afternoon, night and before bedtime
Storage :	Store at room temperature

Product Characteristics:

- Alleviates allergic reactions by blocking histamine H₁ receptors and inhibiting the release of chemical mediators

- Proved to be highly effective in treating ocular itching and hyperemia on conjunctival allergen challenge model of allergic conjunctivitis using cedar pollen as an allergen
- Safety and efficacy confirmed in long-term studies
- No ocular or systemic serious adverse drug reactions
- Possesses liquid properties comparable to those of natural tears

Forward-looking Statements

Information provided in this press release contains so-called “forward looking statements”. The realization 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 conditions are subject to the effects of changes in regulations made by governments in Japan and other nations concerning medical system, drug pricing and other systems, as well as fluctuations in market variables such as interest and foreign exchange rates.