

Santen Files for Manufacturing/Marketing Approval of its Anti-Allergic Ophthalmic Solution DE-114 (Generic name: Epinastine Hydrochloride)

Osaka, Japan, November 27, 2012 --Santen Pharmaceutical Co., Ltd. (Osaka, hereafter Santen) has submitted an application to manufacture and market its anti-allergic ophthalmic solution DE-114 (generic name: epinastine hydrochloride) in Japan on November 21, 2012.

DE-114 is an ophthalmic solution in-licensed from Nippon Boehringer Ingelheim Co., Ltd. and is developed in Japan by Santen, for the indication of allergic conjunctivitis. Epinastine hydrochloride, the active ingredient of DE-114, displays histamine H₁ receptor antagonist activity as its main mechanism, and , inhibits the release/ production of chemical mediators from the mast cells. In Japanese clinical studies, DE-114 has demonstrated its potential to suppress eye itching and conjunctival hyperemia, the main symptoms of allergic conjunctivitis. No serious systemic nor ocular local adverse drug reactions has been found.

Upon obtaining the approval to manufacture and market this drug, Santen is hoping to present another treatment options, thereby contributing to improve the patients' QOL (quality of life).

<Summary>

Development Code	DE-114
Generic Name	Epinastine hydrochloride
Dosage Form	Aqueous ophthalmic solution
Indication	Allergic Conjunctivitis
Dosage	Usually, one drop at a time, 4 times daily (morning, noon, evening and before retiring)