

## **Santen Files for Manufacturing and Marketing Approval of Anti-Allergy Ophthalmic Drug Candidate DE-114A (JAN: Epinastine Hydrochloride)**

September 21, 2018 - Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; Chairman and CEO: Akira Kurokawa; hereinafter, Santen) announced today the filing for manufacturing and marketing approval of anti-allergy ophthalmic drug DE-114A (JAN<sup>\*1</sup>: Epinastine Hydrochloride) in Japan.

DE-114A is an ophthalmic solution based on an in-license from Nippon Boehringer Ingelheim Co., Ltd., and was developed in Japan by Santen as a treatment for allergic conjunctivitis. DE-114A is a higher-dose formulation of Alesion 0.05% Ophthalmic Solution, which has been marketed in Japan since 2013. Epinastine hydrochloride, the active ingredient of DE-114A, blocks histamine H1 receptors as its main mechanism, and inhibits the release and production of chemical mediators from the mast cells. In Japanese clinical studies, DE-114A has demonstrated potential to suppress ocular itching and conjunctival hyperemia, the main symptoms of allergic conjunctivitis. No serious systemic or ocular topical adverse drug reactions have been found.

Allergic conjunctivitis is a conjunctival inflammation which may result when allergens (i.e. substances which induce allergic reactions), such as pollens, contact the surface of the eye. The prevalence of allergic disorders is increasing worldwide. The estimated number of patients with allergic conjunctivitis in Japan is approximately 20 million.\*<sup>2</sup> In the case of allergic conjunctivitis caused by pollens whose high season is predictable, receiving "initial therapy," namely, starting the treatment before airborne pollen levels become elevated could reduce symptoms during the peak pollen season.

Santen expects obtaining the manufacturing and marketing approval of this ophthalmic drug will increase the range of treatment options in medical settings, thereby contributing to the enhancement of patients' quality of life.

#### About DE-114A

|                            |                             |
|----------------------------|-----------------------------|
| JAN                        | Epinastine Hydrochloride    |
| Dosage form                | Aqueous ophthalmic solution |
| Indication (at the filing) | Allergic conjunctivitis     |

\*<sup>1</sup> Japanese Accepted Names for Pharmaceuticals

\*<sup>2</sup> Source: "Allergic Conjunctival Disorders" (in Japanese), the Japanese Ophthalmological Society,

[http://www.nichigan.or.jp/public/disease/ketsumaku\\_allergy.jsp](http://www.nichigan.or.jp/public/disease/ketsumaku_allergy.jsp)

#### **About Santen**

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a nearly 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website ([www.santen.com](http://www.santen.com)).

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