

Santen Announces Receipt of Manufacturing and Marketing Approval of *Alesion*[®] *LX*
Ophthalmic Solution 0.1%, Anti-allergenic Ophthalmic Solution in Japan,
and Conclusion of Joint Sales Promotion Contract concerning *Alesion*[®] and *Alesion*[®] *LX*
with Mitsubishi Tanabe Pharma

September 20, 2019, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (Chairman and CEO: Akira Kurokawa; Head Office: Osaka; hereinafter, “Santen”) announced today that Santen received manufacturing and marketing approval of anti-allergenic ophthalmic solution *Alesion*[®] *LX Ophthalmic Solution 0.1%* (development code: DE-114A; JAN: Epinastine Hydrochloride; hereinafter, “*Alesion LX*”) in Japan.

In addition, Santen and Mitsubishi Tanabe Pharma Corporation (Chuo-ku, Osaka City; President & Representative Director: Masayuki Mitsuka; hereinafter, “Mitsubishi Tanabe Pharma”) concluded a joint sales promotion contract concerning *Alesion*[®] *Ophthalmic Solution 0.05%* (JAN: Epinastine Hydrochloride; hereinafter, “*Alesion*”), which is an anti-allergenic ophthalmic solution currently manufactured and marketed by Santen, and *Alesion LX*, for which Santen has recently obtained approval. Based on this contract, Santen will manufacture and distribute the products, while both companies will conduct promotional activities to medical institutions starting October 1, 2019. Santen will be in charge of medical institutions of ophthalmology, and Mitsubishi Tanabe Pharma will be in charge of medical institutions other than ophthalmology.

Alesion LX 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. *Alesion LX* is a high-dose formulation of *Alesion*, which has been marketed in Japan since 2013. Epinastine hydrochloride, the active ingredient of *Alesion LX*, is histamine H₁ receptor antagonist and suppresses the release of chemical mediators from mast cells. Clinical trials conducted in Japan have demonstrated that the active ingredient of *Alesion LX* can reach the eye tissues in higher amount and work there for a longer time so that eye itching and conjunctival redness as the main symptoms of allergic conjunctivitis can be suppressed by applying twice a day. In addition, no serious side effects have been observed in either the eyes or the entire body.

Santen expects that the joint sales promotion contract between Mitsubishi Tanabe Pharma, which sells the allergy treatment agent *Rupafin*[®] *Tablets 10 mg*, and boasts access to a wide range of medical specialties, and Santen as a specialized pharmaceutical company in the ophthalmic field, will help further

provide medical institutions with *Alesion* and *Alesion LX* and contribute to a better quality of life (QOL) of patients.

Santen has no plans to revise its full-year financial forecast as a result of this announcement. Financial terms of the agreement are not disclosed.

About *Alesion LX*

Product name	<i>Alesion</i> ® <i>LX Ophthalmic Solution 0.1%</i>
JAN	Epinastine Hydrochloride
Dosage form	Aseptic aqueous eye drops
Indication	Allergic conjunctivitis
Dosage	1 drop/time, twice a day (in the morning and evening)

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).

Santen Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is 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 the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

Contact

Corporate Communications Group

Santen Pharmaceutical Co., Ltd.

E-mail: ir@santen.com Tel. : +81-6-4802-9360