

Launch of *Alesion*[®] *LX Ophthalmic Solution 0.1%* in Japan

November 27, 2019, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (Chairman and CEO: Akira Kurokawa; Head Office: Osaka; hereinafter, “Santen”) and Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Masayuki Mitsuka; Head Office: Osaka; hereinafter, “Mitsubishi Tanabe Pharma”) announced today that Santen has launched anti-allergenic ophthalmic solution *Alesion*[®] *LX Ophthalmic Solution 0.1%* (JAN*: Epinastine Hydrochloride; hereinafter, “*Alesion LX Ophthalmic Solution*”) in Japan, for which Santen and Mitsubishi Tanabe Pharma had concluded a joint sales promotion contract .

Based on the joint sales promotion contract announced on September 20, 2019, Santen will manufacture and distribute the newly launched *Alesion LX Ophthalmic Solution* and *Alesion*[®] *Ophthalmic Solution 0.05%* (JAN: Epinastine Hydrochloride; hereinafter, “*Alesion Ophthalmic Solution*”), and Santen and Mitsubishi Tanabe Pharma will jointly conduct promotional activities to medical institutions. In the promotional activities to medical institutions, Santen will be in charge of ophthalmic institutions, and Mitsubishi Tanabe Pharma will be in charge of non-ophthalmic medical institutions.

Alesion LX Ophthalmic Solution 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 Ophthalmic Solution* is a high-dose formulation of *Alesion Ophthalmic Solution*, which has been marketed in Japan since 2013. Epinastine hydrochloride, the active ingredient of *Alesion LX Ophthalmic Solution*, is histamine H₁ receptor antagonist and suppresses the release of chemical mediators from mast cells. The active ingredient of *Alesion LX Ophthalmic Solution* can reach the eye tissues in higher amount and work there for a longer time, therefore, the clinical trials conducted in Japan have demonstrated 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.

As a specialized ophthalmic company, Santen expects that the joint promotional activities with Mitsubishi Tanabe Pharma, which boasts access to a wide range of medical specialties, will help Santen further contribute to a better quality of life (QOL) of patients. Mitsubishi Tanabe Pharma, which sells the allergy treatment agent *Rupafin*[®] *Tablets 10 mg*, believes that the ophthalmic solutions added to the oral medicine will help the company meet more extensive needs of patients. Both companies will strive to conduct fair and appropriate promotional activities in order to contribute to a better QOL of patients and more effective medical treatment for them by offering this new choice of treatment.

Santen and Mitsubishi Tanabe Pharma have no plans to revise their full-year financial forecasts as a result of this product launch.

* Japanese Accepted Names for Pharmaceuticals

Product Characteristics

- *Alesion[®] LX Ophthalmic Solution* is a high-concentration preservative-free formulation of *Alesion[®] Ophthalmic Solution*.
- Compared with *Alesion[®] Ophthalmic Solution*, *Alesion[®] LX Ophthalmic Solution* can keep the epinastine concentration in the conjunctivas higher for a longer time after instillation, with its anti-allergenic effects remaining twice as long as those of the former.
- *Alesion[®] LX Ophthalmic Solution* applied twice a day shows its efficacy for eye itching and conjunctival redness as the main symptoms of allergic conjunctivitis.

Product Name	<i>Alesion[®] LX Ophthalmic Solution 0.1%</i>
JAN	Epinastine hydrochloride
Dosage form	Colorless and clear aseptic aqueous eye drops
Indication	Allergic conjunctivitis
Dosage	1 drop/time, twice a day (in the morning and evening)
Storage	Room temperature
Packaging	5 mL plastic container × 10
Retail Price	712.60 yen/mL
Insurance Notes	None
Approval (Japan)	September 20, 2019
HVL Listing	November 27, 2019
Release (Japan)	November 27, 2019

Product Image



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).

About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed pharmaceutical company in Japan. In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 16-20. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — immuno-inflammation, diabetes and kidney, central nervous system, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. For more information, go to <https://www.mt-pharma.co.jp/e/>

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.

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