



Santen and Mitsubishi Tanabe Pharma announce the conclusion of a contract for the joint sales promotion in Japan of *Alesion*[®] *Eyelid Cream 0.5%*, a new treatment for allergic conjunctivitis

May 7, 2024, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (head office: Osaka; hereinafter Santen) and Mitsubishi Tanabe Pharma Corporation (head office: Osaka; hereinafter Mitsubishi Tanabe Pharma) have announced the conclusion of a contract for the joint sales promotion in Japan of *Alesion® eyelid cream 0.5%*, (generic name: epinastine hydrochloride, development code: STN1011402; hereinafter *Alesion® Cream*), a long-acting treatment for allergic conjunctivitis. Santen received manufacturing and marketing approval for *Alesion® Cream* in Japan in March 2024 and plans to launch the product promptly after the listing of its National Health Insurance price. Under this contract, Santen will manufacture and distribute the product, with both companies detailing medical institutions starting today, May 7, 2024. Santen will be responsible for detailing for ophthalmic medical institutions, with Mitsubishi Tanabe Pharma handling detailing for medical institutions specializing in all other fields. Please note that the contracts between the two companies for the joint sales promotion of the anti-allergic eyedrops "*Alesion® LX Ophthalmic Solution 0.1%*" and "*Alesion® Ophthalmic Solution 0.05%*", which have been in place since 2019, will cease at the end of May 2024 due to expiration of the contract. Santen will be solely responsible for providing drug information services for them from June 2024.

Allergic conjunctivitis is typically treated with anti-allergy eye drops (mediator release inhibitors and histamine H₁ receptor antagonists) which require application to the eyelids twice or four times a day. *Alesion® Cream*, which requires application only once daily to the periocular area (upper and lower eyelids), is the world's first cream treatment for allergic conjunctivitis. It was developed by Santen in the hope that this new formulation will eliminate the burden for patients to take their required dose, thereby improving patient adherence. *Alesion® Cream*'s active ingredient is epinastine hydrochloride, a histamine H₁ receptor antagonist which suppresses the release of chemical mediators from mast cells, making it an effective treatment option for the condition. Phase III Conjunctival Allergen Challenge trial (randomized, double-masked, placebo-controlled trial) performed in Japan on asymptomatic allergic conjunctivitis patients confirmed its superiority to placebo eyelid cream in scores for pruritus and conjunctival hyperemia, main symptoms of allergic conjunctivitis. In addition, a Phase III trial of the long-term administration of the product showed no serious adverse reactions, recording an incidence rate of 1.6% (2/124) for eyelid itchiness and 0.8% (1/124) for eyelid redness.

This contract for the joint sales promotion of *Alesion*[®] *Cream* by Mitsubishi Tanabe Pharma, which sells allergy treatment agent *Rupafin*[®] *Tablets 10 mg* and has access to medical institutions operating in a wide

range of specialist fields, and Santen, a company specializing in eye health, will facilitate the delivery of this new treatment option for allergic conjunctivitis to a larger number of medical institutions, thereby raising patients' quality of life (QOL).

About Alesion® Cream 0.5%

Product name: Alesion® Eyelid Cream 0.5%

Generic name (JAN): Epinastine hydrochloride

Dosage form: Cream

Indication: Allergic conjunctivitis

Dosage: The standard dose is the once daily administration of an appropriate

amount of the cream to the upper and lower eyelids

About Santen

As a specialized company dedicated to eye health, Santen aspires to contribute to the realization of "Happiness with Vision" by providing products and services to patients, consumers, and medical professionals around the world. Since its establishment, and guided by its CORE PRINCIPLE, "Tenki ni sanyo suru," Santen has been committed to helping people maintain and improve their eye health for more than 130 years. Santen is engaged in the global research and development, manufacturing, and sales and marketing of pharmaceutical products in the field of eye care, supporting the eye health of approximately 50 million people in more than 60 countries and regions worldwide. Santen's mission is to provide essential and significant value to patients and society in the prevention, diagnosis, and treatment of eye diseases through products and services created from its expertise in the ophthalmology field and from the patient's perspective. To create a future in which as many patients as possible can lead happy and fulfilling lives, Santen is committed to doing its utmost to realize a society in which people around the world can experience "Happiness with Vision."

For more information, please visit Santen's website https://www.santen.com/en.

About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (MTPC), the pharma arm of Mitsubishi Chemical Group (MCG), is one of the oldest pharmaceutical companies in the world, founded in 1678, and focusing on ethical pharmaceuticals. MTPC is headquartered in Doshomachi, Osaka, the birthplace of Japan's pharmaceutical industry. MCG has positioned health care as its strategic focus in its management policy, "Forging the future". MTPC sets the MISSION of "Creating hope for all facing illness". To that end, MTPC is working on the disease areas of central nervous system, immuno-inflammation, diabetes and kidney, and cancer. MTPC is focusing on "precision medicine" to provide drugs with high

^{*} *Alesion*® is a registered trademark of Boehringer Ingelheim KG.

treatment satisfaction by identifying patient populations with high potential for efficacy and safety. In addition, MTPC is working to develop "around the pill solutions" to address specific patient concerns based on therapeutic medicine, including prevention of diseases, pre-symptomatic disease care, prevention of aggravation and prognosis. For more information, go to https://www.mt-pharma.co.jp/e/

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