



**Santen and Ube Announces U.S. FDA Acceptance of New Drug Application for  
STN10117 (DE-117) (JAN: Omidenepag Isopropyl)  
as a Treatment for Patients with Glaucoma and Ocular Hypertension**

February 2, 2021, Osaka and Ube, Japan - Santen Pharmaceutical Co., Ltd. (hereinafter “Santen”) and Ube Industries, Ltd. (hereinafter “Ube Industries”) announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for STN10117 (DE-117) (JAN: Omidenepag Isopropyl), an investigational topical ophthalmic solution, a treatment for patients with glaucoma and ocular hypertension. Based on the Prescription Drug User Fee Act (PDUFA), the FDA is reviewing the NDA upon setting November 19, 2021 as the goal date for completing the review process.

Santen and Ube Industries have been co-developing STN10117 (DE-117) as an ophthalmic solution to treat glaucoma and ocular hypertension. Omidenepag Isopropyl, the active pharmaceutical ingredient in STN10117 (DE-117), licensed out from Ube Industries to Santen, is the selective EP2 receptor agonist and is an ocular hypotensive agent with a new mechanism of action. After launching STN10117 (DE-117) in November 2018 in Japan as *EYBELIS Ophthalmic Solution 0.002%*, Santen and Ube Industries have, in a phased manner, filed for the treatment’s marketing approval also in Asia, earning a green light in countries such as South Korea from December 2019.

Glaucoma is a disease that causes damage to the optic nerve, leading to visual field loss. Since the disease is generally progressive and irreversible, early detection and treatment to control the progression of such damage and visual field defects are crucial in treatment, and lowering intraocular pressure is the most effective means of avoiding glaucomatous damage. Glaucoma is the primary cause of eye-disease-induced visual impairment (e.g., failing/loss of eyesight) in Japan, and, in the U.S., more than 3 million people suffer from this disease<sup>1</sup> and it is said that the number of people with glaucoma worldwide reach 70.6 million <sup>2</sup>.

Santen and Ube Industries expect that providing a greater number of treatment options to the frontlines of healthcare will contribute to improving the quality of U.S. patients’ lives.

1 Glaucoma Research Foundation. Glaucoma Facts and Stats. <https://www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php>.

Accessed August 22, 2019.

2 World report on vision. Geneva: World Health Organization; 2019..

**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 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)).

#### **About Ube Industries, Ltd.**

Ube Industries (Head office: Ube City, Yamaguchi Prefecture; President: Masato Izumihara) is a chemistry-focused company that is also engaged in the construction materials and machinery businesses. In its pharmaceutical business, Ube Industries aims to contribute to better health for everyone with community-based manufacturing of drugs using innovative technologies. Going forward, Ube Industries will continue creating promising new compounds for new medicines with a dual approach of pursuing drug discovery through internal and joint research and development projects, and manufacturing and supply of APIs and intermediates. For more details, please see Ube Industries' website (<http://www.ube-ind.co.jp/ube/en/>).

#### **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.

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