Santen and UBE announces U.S. Food and Drug Administration accepts resubmission of NDA for STN1011700 / DE-117 (omidenepag isopropyl) for treating glaucoma and ocular hypertension

June 10, 2022, Santen Pharmaceutical Co., Ltd. (head office in Osaka; hereinafter "Santen") and UBE Corporation. (head office in Ube; hereinafter "UBE") are pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted the resubmitted New Drug Application (NDA) for STN1011700 / DE-117 (omidenepag isopropyl) for the treatment of glaucoma and ocular hypertension on June 8, 2022 (Pacific Standard Time). Based on the Prescription Drug User Fee Act (PDUFA[1]), the FDA is reviewing the NDA upon setting November 6, 2022 as the goal date for completing the review process.

STN1011700 / DE-117 (hereinafter DE-117) is an ophthalmic solution, developed jointly by Santen and UBE, for treating glaucoma and ocular hypertension. Omidenepag Isopropyl, the active pharmaceutical ingredient in DE-117, has a new mechanism of action, acting selectively on EP2 receptor agonist to lower intraocular pressure. It was launched in Japan as *Eybelis* ophthalmic solution 0.002% in November 2018, and was filed for marketing approval in Asian countries in stages. The product was released in South Korea and other countries in February 2021 and thereafter.

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. Lowering intraocular pressure is currently the most effective treatment option. Glaucoma is the primary cause of eye-disease-induced visual impairment (e.g., failing/loss of eyesight) in Japan. There are more than 3 million people with glaucoma in the United States[2], and was estimated to reach 76 million worldwide in 2020[3]. The two companies strive to offer a greater number of treatment options to the healthcare providers that contribute to improving the quality of life in patients in the United States.

The NDA has been resubmitted after addressing all findings pointed out in FDA's Complete Response Letter, received in November 2021.

1 Prescription Drug User Fee Act: A U.S. law for promoting the approval of innovative drugs, enacted in 1992

2 The Eye Diseases Prevalence Research Group, Arch Ophthalmol. 2004; Prevent Blindness America

3 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, and its products now reach patients in over 60 countries and regions.

Toward realizing “WORLD VISION” (Happiness with Vision), the world Santen ultimately aspires to achieve, as a “Social Innovator”, we aim to reduce the social and economic opportunity loss of people around the world caused by eye diseases and defects by orchestrating and mobilizing key technologies and players around the world.

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 (https://www.santen.com/en/).

About UBE Corporation.

Leveraging the manufacturing technologies the UBE groups has cultivated, UBE creates the value required by society, in the safe and environmentally friendly manner demanded by society, and delivers that value to the people.

UBE helps to solve global environmental issues, which have become a common issue for all humankind, and contribute to people's lives and health, and an enriched future society. UBE aims to contribute to better health for everyone with community-based manufacturing of drugs using innovative technologies. Going forward, UBE 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 Corporation’s 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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