Santen and UBE Received FDA Approval for *OMLONTI*® (Omidenepag Isopropyl Ophthalmic Solution) 0.002% for the Reduction of Elevated Intraocular Pressure in Patients with Primary Open-Angle Glaucoma or Ocular Hypertension

September 26, 2022, Santen Pharmaceutical Co., Ltd. (head office in Osaka; hereinafter "Santen") and UBE Corporation (head office in Ube; hereinafter "UBE") today announced that the U.S. Food and Drug Administration (FDA) has approved *OMLONTI*® (omidenepag isopropyl ophthalmic solution) 0.002% eye drops for the reduction of elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension. The approval date was September 22.

OMLONTI® is developed jointly by Santen and UBE. Omidenepag isopropyl, the active pharmaceutical ingredient in *OMLONTI*®, developed by UBE, is a relatively selective prostaglandin EP2 receptor agonist, which increases aqueous humor drainage through the conventional (or trabecular) and uveoscleral outflow pathways, and the only product with this pharmacological action. *OMLONTI*® 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 five countries and regions beginning in February 2021.

"Glaucoma prevalence is increasing as the global population ages. Supporting patients by protecting vision across the continuum of clinical care in glaucoma is a significant aim for Santen to reduce the social and economic opportunity loss of people around the world caused by eye conditions," explains Peter Sallstig, Chief Medical Officer of Santen. "This approval is an important milestone in our ambition to tackle unmet needs in eye health and advances our goal of realization of "Happiness with Vision". It also represents our first glaucoma offering in the U.S. We are pleased to provide doctors and patients in the U.S. with a new option to help control IOP for the more than three million Americans affected by glaucoma[1] or ocular hypertension."

"UBE Corporation is committed to working on new drug discoveries on a daily basis with the aim of providing patients with more treatment options for diseases with high unmet needs," said Yoichi Funayama, Senior Executive Officer and General Manager of the Pharmaceutical Division, UBE Corporation. "We are very pleased that this ophthalmic solution has been approved for glaucoma in the U.S., following approvals in Japan and Asia. We have high expectations that omidenepag isopropyl will provide a new treatment option for more patients suffering from glaucoma and ocular hypertension through Santen."

The FDA approval for *OMLONTI*® was based on data from 12 clinical studies conducted in multiple global

locations. Notably, a U.S. Phase 3 study confirmed *OMLONTI*® to be non-inferior to timolol, the standard of care. Two different Phase 3 studies conducted in Japan and Asia showed *OMLONTI*® to be non-inferior to latanoprost, another standard of care.

Glaucoma causes damage to the optic nerve resulting in visual field loss, and remains a leading cause of irreversible blindness worldwide.[2] Since the disease is generally progressive, early detection and treatment to control the progression are crucial, and lowering IOP is the most effective means of avoiding damage to the optic nerve. The estimated number of patients globally in 2020 was 76 million, and it is expected to increase to 95 million by 2030.[3] Primary open-angle glaucoma is the most common type of glaucoma. Ocular hypertension, which affects millions, can lead to glaucoma and vision loss if untreated. [4]

“Treatments that focus on IOP reduction help to slow or prevent further loss of vision for those with glaucoma or ocular hypertension. However, not all patients respond to the same treatments, and some may not have successful outcomes,” said Jason Bacharach, MD, Medical and Research Director at North Bay Eye Associates, Inc. “The approval of omidenepag isopropyl ophthalmic solution 0.002% provides doctors with another safe and effective option to use when treating patients with these sight-threatening conditions.”

References:

1. Glaucoma Research Foundation. Glaucoma Facts and Stats. Available at https://www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php. Accessed July 26, 2022.
2. Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. Br J Ophthalmol. 2006;90(3):262-267. doi:10.1136/bjo.2005.081224.
3. World report on vision. World Health Organization World report on vision (who.int). Last accessed September 2022.
4. American Academy of Ophthalmology. What is Ocular Hypertension. Available at https://www.aao.org/eye-health/diseases/what-is-ocular-hypertension. Accessed July 26, 2022.

About Santen

As a specialized company dedicated to eye health 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”, Santen aims 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 (https://www.ube.co.jp/ube/en/).

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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