



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

OMLONTI[®] is the 2nd FDA-approved product from Santen in the last 15 months for patients in the U.S. with vision conditions

September 26, 2022, Emeryville, Calif. and Ube, Japan – Santen Inc., the U.S. subsidiary of Santen Pharmaceutical Co., Ltd. (Santen), and UBE Corporation (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 glaucoma¹ 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.”

OMLONTI[®] was evaluated in three randomized and controlled clinical trials in subjects with open-angle glaucoma or ocular hypertension with average baseline IOP of 24-26 mm Hg. The double-masked treatment duration was three months in all three studies. The third study included a 9-month open-label treatment period following the 3-month double-masked treatment period. In the three studies, IOP reductions were observed for all treatment arms. In the *OMLONTI*[®] arm, the reduction in IOP ranged from 5-7 mm Hg across all three studies. The corresponding reductions for the timolol and latanoprost arms were 5-7 mm Hg and 6-8 mm Hg, respectively.

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.”

Indication

OMLONTI[®] (omidenepag isopropyl ophthalmic solution) 0.002%, is a relatively selective prostaglandin E2 (EP2) receptor agonist, indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

The safety of *OMLONTI*[®] has been evaluated in 12 clinical studies, 10 of which investigated the safety of *OMLONTI*[®] in QD dosing. The results from these clinical trials indicate that *OMLONTI*[®] is safe and well tolerated by adult subjects (N=1111) with a diagnosis of open-angle glaucoma or ocular hypertension, and by pediatric subjects (N=6) with juvenile open-angle glaucoma. The risks identified with instillation of *OMLONTI*[®] include macular edema, including CME, in patients with aphakia, pseudophakia, or other risk factors for macular edema; ocular inflammation; the possibility of increased eye pigmentation; and eyelash changes.

About Santen

As a global specialized company dedicated to eye health, Santen brings a more than 130-year history of scientific knowledge and organizational capabilities to research, development, and commercialization of pharmaceutical, surgical, and OTC eye care products. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan, and its products now reach patients in more than 60 countries. 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 websites www.santenusa.com and www.santen.com (Japan headquarters).

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/>).

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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- 1 Glaucoma Research Foundation. Glaucoma Facts and Stats. Available at <https://www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php>. Accessed September 22, 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 22, 2022.
- 4 American Academy of Ophthalmology. What is Ocular Hypertension. Available at <https://www.aao.org/eye-health/diseases/what-is-ocular-hypertension>. Accessed September 22, 2022.