Santen and Ube Industries Announce Launch of Glaucoma and Ocular Hypertension Treatment *EYBELIS Ophthalmic Solution 0.002%* in Japan

November 27, 2018 - Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; hereinafter, "Santen") and Ube Industries, Ltd. (Head Office: Ube; hereinafter, "Ube Industries") announced today the launch of glaucoma and ocular hypertension treatment *EYBELIS Ophthalmic Solution 0.002%* (JAN*: Omidenepag Isopropyl; hereinafter, "*EYBELIS*") in Japan.

Santen and Ube Industries co-developed *EYBELIS* as a treatment for glaucoma and ocular hypertension. Omidenepag Isopropyl, the active pharmaceutical ingredient in *EYBELIS*, is the world's first selective EP2 receptor agonist and is an ocular hypotensive agent with a new mechanism of action.

Glaucoma is a disorder which causes optic nerve damage leading to visual field loss, and is a major cause of visual impairment including decreased vision and blindness in Japan. Since glaucomatous optic nerve damage and visual field defects are generally progressive and irreversible, early detection and treatment for controlling progression of damage is crucial in the treatment of glaucoma. *EYBELIS* is shown to contribute to the lowering of intraocular pressure (IOP), the most effective means of avoiding glaucomatous damage.

Director, Executive Corporate Officer of Japan Business, and head of Japan Sales and Marketing, Prescription Pharmaceuticals Takeshi Ito of Santen says, "*EYBELIS* is an eye drop treatment based on a world-first mechanism of action and research has verified the non-inferior IOP-lowering effect of *EYBELIS* ophthalmic solution 0.002% against latanoprost ophthalmic solution 0.005%. *EYBELIS* is an ophthalmic solution that has the potential to become a first-line treatment using a new mechanism of action, and I am expecting this product will meet unmet needs that exist in current glaucoma therapies. Santen aims at further helping patients by providing appropriate drug information and leveraging the strengths we have nurtured in ophthalmology and our Japan business in particular."

Executive Officer, General Manager of Pharmaceutical Division Yasushi Konno of Ube also mentions, "Ube is engaged in producing a new drug form our region with abundant technical innovation and aims to contribute to better health for everyone. Omidenepag Isopropyl is the outcome of our efforts in medicinal chemistry and CMC technology, which we have cultivated for many years. To further contribute to health care, we will continue discovering and developing new chemical entities that can be seeds for new medicinal products."

Santen and Ube Industries will make *EYBELIS* available in medical settings as a new treatment option, and will provide drug safety information for patients and healthcare professionals, in order to promote understanding of the appropriate use of *EYBELIS*, thereby enhancing patients' quality of life.

Santen and Ube have no plans to revise their full-year financial forecasts as a result of this announcement.

* Japanese Accepted Names for Pharmaceuticals

Product Characteristics

- *EYBELIS* is an ophthalmic solution for glaucoma and ocular hypertension treatment which is a selective EP2 receptor agonist.
- Demonstrated that *EYBELIS* stably maintains efficacy in long term clinical study.
- Demonstrated non-inferiority to latanoprost 0.005% in a clinical trial where primary endpoint was IOP lowering.
- Demonstrated significant effect in non-/low-responders treated with other medications, after switching to *EYBELIS*.

Product Name	*EYBELIS Ophthalmic Solution 0.002%*
Generic Name	Omidenepag Isopropyl
Formulation	Sterilized aqueous ophthalmic solution
Indication	Glaucoma and ocular hypertension
Dosage	1 drop/time, once daily
Storage	Tight container. Store in the original carton until time of use to protect from light. Refrigerate *EYBELIS* at 2ºC to 8ºC (36ºF to 46ºF).
Packaging	2.5mL plastic containers × 5, 2.5mL plastic container × 10
Retail Price	945.30JPY per 1 mL
Insurance Notes	None
Approval (Japan)	September 21, 2018
HVL Listing	November 20, 2018
Release (Japan)	November 27, 2018

Product Image



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 nearly 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).

About Ube Industries

Centering on Chemicals business, Ube Industries operates Pharmaceutical / Cement & Construction Materials / Machinery / Energy & Environment businesses. Among them, the pharmaceutical business is positioned as one of active growth businesses of the company. Ube Industries endeavors to expand the pharmaceutical business by both "drug discovery" by its own / joint research and development, and "manufacturing of APIs and intermediates." For more details, please see Ube Industries' 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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