



Santen and Ube Industries Announce Receipt of Manufacturing and Marketing Approval for Glaucoma and Ocular Hypertension Treatment *EYBELIS* Ophthalmic Solution 0.002% in Japan

September 21, 2018 - Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; hereinafter, "Santen") and Ube Industries, Ltd. (Head Office: Ube; hereinafter, "Ube Industries") announced today that Santen has received manufacturing and marketing approval of glaucoma and ocular hypertension treatment *EYBELIS* Ophthalmic Solution 0.002% (development code: DE-117; 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 a selective EP2 receptor agonist and is a new mechanism of action as an ocular hypotensive agent.

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.

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.

EYBELIS is a product in global development, and is currently in Phase 3 trials in Asia (outside Japan). Phase 3 trials for *EYBELIS* in the U.S. are scheduled to start in the second half of fiscal 2018.

* Japanese Accepted Names for Pharmaceuticals

About EYBELIS

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| Product name | <i>EYBELIS Ophthalmic Solution 0.002%</i> |
| JAN: | Omidenepag Isopropyl |
| Dosage form | Sterilized aqueous ophthalmic solution |
| Indication | Glaucoma and ocular hypertension |
| Dosage | 1 drop/time, once daily |

<Characteristics>

- Omidenepag Isopropyl is a selective EP2 receptor agonist and a new mechanism of action as an ocular hypotensive agent. An Anatomical Therapeutic Chemical (ATC) code approved by the WHO Collaborating Centre for Drug Statistics Methodology was assigned for Omidenepag Isopropyl, based on its new mechanism of action which was determined to be different from existing mechanisms of existing IOP lowering agents.
- While existing FP receptor antagonists mainly promote the outflow of aqueous humor through the uveoscleral outflow pathway, EYBELIS enhances the outflow of aqueous humor through both the uveoscleral outflow and the trabecular outflow pathways, thereby demonstrating powerful and stable IOP lowering effect.

*Based on nonclinical data

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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