Santen and Ube Industries receives Complete Response Letter from FDA for STN1011700/DE-117 - citing contract manufacturer's non-compliance with current Good Manufacturing Practice (cGMP)

November 18th, 2021, Osaka and Ube, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) and Ube Industries, Ltd. (hereinafter Ube Industries) received a complete response letter (CRL) from the US Food and Drug Administration (FDA) regarding its application for STN1011700/DE-117 for the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension (OHT).

According to the CRL, the FDA has identified deficiencies at contract manufacturing facilities used for STN1011700/DE117 as not fully complying with current Good Manufacturing Practice (cGMP) regulations, but it does not specifically about manufacturing process of STN1011700/DE117.

Santen and Ube Industries will continue to work closely with the FDA to determine the appropriate next steps for this New Drug Application. We remain confident that the deficiencies at the manufacturing facilities will be resolved to enable us to obtain approval for STN1011700/DE-117 as a potential treatment option for people with glaucoma in the United States.

Santen and Ube Industries have been co-developing STN1011700/DE-117 as an ophthalmic solution to treat glaucoma and ocular hypertension. Omidenepag Isopropyl, the active pharmaceutical ingredient in STN1011700 /DE-117, licensed out from Ube Industries to Santen, is the selective EP2 receptor agonist and is an ocular hypotensive agent with a new mechanism of action. After launching STN1011700/DE-117 in November 2018 in Japan as EYBELIS Ophthalmic Solution 0.002%. It is commercially available in several countries in Asia, including Japan and South Korea.

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