Press Release

Santen filing accepted by European Medicines Agency (EMA) for review of application for marketing authorization of the use of STN1013001 cationic emulsion of latanoprost 50µg/mL in glaucoma

October 6, 2022, Santen Pharmaceutical Co., Ltd. (Head Office: Osaka; hereinafter "Santen") announced the European Medicines Agency (EMA) has accepted for review the marketing authorization application for the use of STN1013001 for lowering of intraocular pressure (IOP) in open-angle glaucoma and ocular hypertension.

Ocular surface disease (OSD) represents an emerging problem in the management of glaucoma, with up to 60% of glaucoma patients having dry eye.[1] OSD is a multifactorial ocular condition that may involve tear film degradation as well as damage to the ocular surface.[2] It negatively influences quality of life and compromises adherence to glaucoma eye drop treatment, which can influence the efficacy of the therapy.[3,4]

STN1013001 is preservative-free latanoprost 50µg/mL presented in a lipid-containing cationic emulsion, a technology in which the positively-charged emulsion droplets are attracted onto the negatively-charged ocular surface to increase its spreading and residence time on the ocular surface.[5] This patented cationic emulsion technology, developed by Santen, improves the tear film lipid layer surface properties[6] and used as the core technology for other marketed products in more than 30 countries, including in artificial tears for dry eye disease. Latanoprost reduces elevated IOP[7] and is Europe's most prescribed prostaglandin analogue.[8]

The marketing authorization application is based on a clinical package including positive results from a phase III clinical trial conducted in Europe and Asia – a non-inferiority trial of STN1013001 (cationic emulsion of latanoprost 50µg/mL) versus latanoprost 50µg/mL. The IOP lowering efficacy of STN1013001 was established by demonstrating its non-inferiority to latanoprost 50µg/mL at both 9 am and 4 pm time points at week 12. In addition, both time points at week 4 also achieved the same criteria of non-inferiority as week 12. The superiority of STN1013001 in improving OSD (secondary endpoint) was demonstrated versus latanoprost with a significant improvement in corneal fluorescein staining (CFS) score at week 12.[9]

"Despite the progress in the understanding of glaucoma and the many possible treatment options, there is an increasing appetite for innovation as we still see the disease progressing and causing

much vision loss across the world. This combination of effective IOP lowering alongside the potential to protect and improve the ocular surface is a development that we hope can help many patients who find eye drop treatments challenging – adherence can be poor, quality of life impacted and rates of failure of glaucoma surgery greater than we would wish," says Professor Christophe Baudouin, MD, PhD, Professor and Chairman of Ophthalmology at Quinze-Vingts National Ophthalmology Hospital, Paris, and principal investigator of the phase III study.

"We are excited to continue building out Santen's rich heritage in glaucoma by bringing an additional option to patients and physicians. Many glaucoma patients suffer from ocular surface disease and would welcome an option that also aims to address this condition. Today's announcement is another example of Santen delivering 'Happiness with Vision'" said Peter Sallstig, Chief Medical Officer, Santen.

"This innovation is something Santen is very proud of since the cationic emulsion technology was developed by our R&D team here in the EMEA region," says Luis Iglesias, President and Head of Santen EMEA and North America. "We are hopeful of bringing this innovative product to patients as a treatment for glaucoma while also tackling unmet needs in ocular surface disease."

About glaucoma

Glaucoma causes damage to the optic nerve, leading to visual field loss, and it remains the leading cause of irreversible blindness worldwide.[10,11] Since the disease is generally progressive and irreversible, early detection and treatment to control the progression are crucial, and lowering intraocular pressure is an effective means of avoiding damage to the optic nerve**.** The estimated number of patients globally in 2020 was 76 million, and this is expected to increase to 95 million by 2030.[12]

References

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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/).

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