

Santen Announces China NMPA Acceptance of STN1011101 Marketing Authorization Application in Patients with Open-Angle Glaucoma or Increased Intraocular Eye Pressure

February 8, 2023 - Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter Santen) announced that the National Medical Products Administration (NMPA) of China, has accepted the marketing authorization application for STN1011101, a preservative-free combination eye drop of tafluprost 0.0015% (co-developed by Santen and AGC Inc. (head office: Chiyoda-ku, Tokyo)) and timolol 0.5%. STN1011101 is for lowering intraocular pressure of patients with open-angle glaucoma or ocular hypertension, targeting patients who require combination therapies because topical beta-blockers or prostaglandin derivatives monotherapies are ineffective, and patients who may benefit from the use of preservative-free eye drops. The drug will address an unmet need for glaucoma treatment in China and provide a new treatment option for patients.

Glaucoma causes damage to the optic nerve, leading to visual field loss, and it remains the leading cause of visual impairment including blindness worldwide.^{1,2} Since the disease is generally progressive and irreversible, early detection and treatment to control the progression are crucial, and lowering intraocular pressure is manageable 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 2030.³ The “Chinese Glaucoma Guidelines 2020” states that if target intraocular pressure cannot be achieved from monotherapies, drugs with different mechanisms of action may be used in combination. If a combination is needed, a fixed dose combination formulation is preferred.

The active metabolite of tafluprost (tafluprost acid), an active pharmaceutical ingredient in this formulation, is a prostanoid FP receptor agonist, while the other ingredient, timolol maleate, is a nonselective β -receptor blocker. Both drugs have different mechanisms of action to lower interocular pressure and are positioned as first-line treatments in China. Santen will strengthen its tafluprost product portfolio by adding this combination drug to the existing tafluprost monotherapy drug.

Since September 2013, when it was approved in Japan for marketing as *Tapcom*[®] Combination Ophthalmic Solution, the combination eye drop of tafluprost 0.0015% and timolol 0.5% has been approved in 48 countries and regions worldwide, including Japan, Europe and Asia, and through this new drug application, a new treatment option will be offered to healthcare professionals in China when approved. Santen will continue to seek to make contributions from the patient's perspective, including enhancing the convenience of eye drops for glaucoma patients.

References

1. Flaxman S et al. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. *The Lancet Global Health* (2017) 5: e1221–34
2. Steinmetz JD et al. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study. *The Lancet Global Health* (2020) 9: e144-60
3. World report on vision. World Health Organization World report on vision (who.int) Last accessed Sept 2022

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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