December 22, 2025

General Announcement

Senju Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd.

Obtained manufacturing and marketing approval in Japan for Avarept®
Ophthalmic suspension 0.3%, a novel treatment of Dry Eye Disease
through Transient Receptor Potential cation channel subfamily V member 1 Inhibition

Senju Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Mr. Shuhei Yoshida; hereinafter: Senju) is pleased to announce that "Avarept® Ophthalmic suspension 0.3%" (Generic Name: Motugivatrep, development code: SJP-0132, hereinafter: Product), discovered and licensed by Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan; President: Mr. Naoyuki Mochida; hereinafter: Mochida) and developed by Senju as an eye drop treatment for Dry Eye Disease (DED), has obtained manufacturing and marketing approval in Japan as of December 22, 2025.

Avarept® Ophthalmic suspension 0.3% represents a novel therapy for DED with Transient Receptor Potential cation channel subfamily V member 1 (TRPV1)[*1] antagonist, designed to improve both subjective symptoms and objective signs of DED through inhibition of TRPV1. A pivotal Phase III clinical trial conducted by Senju (Study Name: 3-02 clinical trial[*2]) successfully met the primary endpoint by demonstrating statistically significant improvement in dry eye symptom severity, as measured by a 15-item patient-reported questionnaire, the Dry Eye-Related Quality-of-Life Score (DEQS)[*3]. This achievement marks the world's first successful clinical development of a TRPV1 antagonist for DED, completed in Japan.

DED, the target disease of SJP-0132, is defined as "A multifactorial disease characterized by an unstable tear film causing discomfort and/or visual impairment, accompanied by ocular surface disorder" [1)]. Recently, the number of DED patients has been increasing due to an aging population, the long-term use of contact lenses, and the widespread use of Visual Display Terminals (VDT) such as PCs and Smartphones.

Takuro Sekiya, "Executive Officer, Head of R&D Division", said: "Chronic dryness and discomfort associated with dry eye disease impose a significant burden on patients and often interfere with their daily lives. We are therefore delighted that the approval of this Product enables us to offer a new treatment option that addresses these unmet medical needs. We sincerely hope that Avarept® will help improve DED symptoms and enhance the Quality of life for as many DED patients as possible and contribute to the advancement of DED therapy".

Yasushi Taguchi, "Executive Officer, Head of Research Division", said: "I am very pleased that Avarept®, the world's first drug discovered by Mochida that inhibits TRPV1, has received manufacturing and marketing approval. I hope this Product will improve the unpleasant symptoms for DED patients and lead to an enhanced Quality of life.

Senju is committed to commercial launch to provide patients with new options for alleviating the signs and symptoms of this disease.

Mochida is dedicated to leveraging its foresight and innovation to further its involvement in drug discovery research, and thereby continue its contributions toward improving the Quality of life for patients.

*1 TRPV1

A cation channel responds to and is activated by stimuli including capsaicin, heat, inflammatory mediators, and osmotic pressure. In individuals with DED, elevated tear film osmolarity and increased concentrations of inflammatory mediators are well-documented. It is hypothesized that these conditions lead to the activation or sensitization of TRPV1 channels [2)], consequently reducing the activation threshold of corneal sensory nerves [1)].

*2 3-02 clinical trial

A Phase III, multicenter, randomized, double-masked, placebo-controlled, parallel-group study in patients with DED

*3 DEQS : Dry Eye-related Quality of life Score

A 15-item patient-reported questionnaire that measures the severity of dry eye symptoms and their impact on daily activities, available for evaluating several aspect of Quality of life including mental health[3)]

1) : “Dry Eye Diagnostic Guidelines” Japan Dry Eye Society (2019)
2) : Z. Pan et al. Invest Ophthalmol Vis Sci. 2011; 52(1): 485-93., P. Rozas et al. Pain 2016; 157(6):1346-62.
3) : Y. Sakane et al. JAMA Ophthalmol. 2013;131(10):1331-1338.

Product Overview

Product Name	Avarept® Ophthalmic suspension 0.3%
Generic Name	Motugivatrep
Active Ingredients	Motugivatrep 3mg per 1mL
Efficacy and Effects	Dry Eye Disease (DED)
Dosage	1 drop at a time, 4 eye drop per day
Approval date	December 22, 2025

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