

July 8, 2024

General Announcement:

Senju Pharmaceutical Co., Ltd.

**Notice of Orphan Drug Designation for SJP-0008 as a Treatment of Central Retinal Artery Occlusion**

Senju Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Mr. Shuhei Yoshida; hereinafter “Senju”) hereby announces that the orphan drug designation to the in-house developed compound having the development code SJP-0008 was granted by the Ministry of Health, Labor and Welfare (HMLW) on June 19, 2024, as an orphan drug of the Central Retinal Artery Occlusion (CRAO).

Orphan drugs are designated by the MHLW after consultation with the Pharmaceutical Affairs and Food Sanitation Council as drugs to treat a disease affecting less than 50,000 patients in Japan, with particularly high medical needs. This designation can be expected to shorten the period required for regulatory approval, resulting in early approval and launch.

CRAO, the therapeutic target of SJP-0008, occurs when central retinal artery occlusion leads to irreversible impairment of visual field and vision loss. Approximately 90% of patients suffer severe visual impairment, resulting in less than 0.1 in decimal visual acuity<sup>(1)</sup>. However, no guidelines or evidence-based therapies have been established anywhere in the world for CRAO<sup>(2)</sup>.

Senju will work diligently to develop SJP-0008 as a new therapy for such a serious disease with the aim of obtaining manufacturing and marketing approval.

The development of SJP-0008 is to be carried out with funding under the program Cyclic Innovation for Clinical Empowerment (CiCLE) established by the Japan Agency for Medical Research and Development (AMED).

(1) Hayreh SS, and Zimmerman MB. Central retinal artery occlusion: visual outcome. Am J Ophthalmol 2005; 140: 376–391.

(2) Chronopoulos A and Schutz JS. Central retinal artery occlusion - A new, provisional treatment approach. Surv Ophthalmol. 2019; 64: 443-51.

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