

Port Delivery System with Ranibizumab Demonstrates Results Phase I/II Trial for Neovascular Age-related Macular Degeneration and Diabetic Macular Edema in Japan

- In patients with neovascular age-related macular degeneration and diabetic macular edema, Port Delivery System with Ranibizumab has confirmed a similar trend in efficacy as in previous overseas clinical trials
- In patients with neovascular age-related macular degeneration, Port Delivery System with Ranibizumab has confirmed a similar safety profile as in previous overseas clinical trials
- First innovative intraocular implant for the treatment of nAMD and DME in Japan with long-term effects and reduced treatment burden by refilling the ocular implant with drug every six months
- Chugai will file a new drug application in Japan based on the study results and the overseas Phase III clinical studies conducted by Roche

TOKYO, November 25, 2025 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that the results of a phase I/II study (TEIEN study) in Japan to evaluate the efficacy and safety of Port Delivery System with Ranibizumab (PDS), in patients with neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). In terms of efficacy, the meaning change from baseline in best-corrected visual acuity (BCVA) score at 24 weeks was -1.4 letters (95%CI: -5.7, 2.9) in the nAMD patient population. The safety profile was similar to previous overseas clinical trials in the nAMD and DME patient populations.

“The current standard of care for nAMD and DME requires intraocular injections at intervals of 4 to 16 weeks, and a less burdensome treatment for patients is desired. The PDS is expected to maintain long-term efficacy and reduce the burden of treatment by using an innovative intraocular implant that is the first of its kind in Japan and only requires refills with the drug once every 24 weeks. This is a major advancement for patients with nAMD and DME, and represents a new treatment option that can also benefit physicians and patients’ families. We are committed to working diligently toward filing for approval in Japan so that we can deliver this innovative value to patients as soon as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

Chugai will file a new drug application in Japan based on the study results, and the results of overseas phase III clinical trials conducted by Roche for patients with nAMD (Archway study) and DME (Pagoda study).

About Japanese Phase I/II Study for Port Delivery System with Ranibizumab

This study is a domestic phase I/II clinical trial to evaluate the efficacy and safety of the Port Delivery System with Ranibizumab. It consists of two cohorts: a cohort of Japanese patients with neovascular age-related macular degeneration (nAMD) and a cohort of Japanese patients with diabetic macular edema (DME). Fifteen patients were enrolled in the nAMD cohort and six patients in the DME cohort. The primary endpoints are safety and tolerability in both patient populations, and the mean change from baseline in the best-corrected visual acuity (BCVA) score at 24 weeks in the nAMD patient population.

About Port Delivery System with Ranibizumab

The Port Delivery System with Ranibizumab (PDS) is an intraocular implant designed to provide long-term and sustained release of drugs into the eye.¹⁻⁴⁾ It comprises the ocular implant which is surgically placed into the eye during a one-time surgical procedure, and four ancillary devices to initially fill, insert, refill, and remove the implant (if needed). It is the first system in Japan. The PDS continually delivers a customized formulation of ranibizumab into the back of the eye.⁵ Ranibizumab is a VEGF inhibitor designed to bind to and inhibit VEGF-A, a protein that has been shown to play a critical role in the formation of new blood vessels and the leakiness of the vessels in patients with retinal vascular disorders, including nAMD and DME.^{1-3,6)} Port Delivery System with Ranibizumab only requires refills with the drug every 24 weeks for patients with nAMD or DME, compared to intravitreal VEGF therapies which can require injections as often as every 4 to 16 weeks. Reducing the frequency of administration is expected to lessen the treatment burden for patients, their families, and medical institutions.

About neovascular age-related macular degeneration (nAMD)

Age-related macular degeneration (AMD) is a condition that affects the part of the eye that provides sharp, central vision needed for activities like reading and driving. Neovascular or “wet” AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss if left untreated.⁷⁻⁹⁾ It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.⁹⁾ Worldwide, around 20 million people are living with nAMD – the leading cause of vision loss in people over the age of 60 – and the condition will affect even more people around the world as the global population ages.^{7,10,11)}

About diabetic macular edema (DME)

Affecting around 29 million people globally, DME is a vision-threatening retinal condition associated with blindness and decreased quality of life when left untreated.¹²⁻¹⁵⁾ DME occurs when damaged blood vessels leak into and cause swelling in the macula.^{16,17)} The number of people with DME is expected to grow as the prevalence of diabetes increases.¹⁸⁾

Sources

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