News Release

Chugai Files for the Medical Device Component of the Port Delivery Platform with ranibizumab in Japan

- Application filed in Japan for the medical device component (ocular implant and ancillary devices) in combination with the Port Delivery Platform when used with ranibizumab
- In addition to this device application, a filing for the customized ranibizumab formulation (drug product) used in the ocular implant is planned in 2026, with the aim of obtaining approvals for both the device and the drug
- The ocular implant provides sustained efficacy for 24 weeks (approximately six months) and is expected to enable less frequent dosing and clinic visits, and reduce the burden on patients, their families, and healthcare providers

TOKYO, March 19, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced that it filed a regulatory application with the Ministry of Health, Labour and Welfare (MHLW) for the medical device component (implant and ancillary devices; hereafter, the “ocular implant”) of the Port Delivery Platform with ranibizumab when used in combination with of ranibizumab.

The application is based on the results from the global Phase III Archway study in patients with neovascular age-related macular degeneration (nAMD), and the global Phase III Pagoda study in patients with diabetic macular edema (DME), both conducted in the US by Roche/Genentech.

The Port Delivery Platform with ranibizumab can be commercialized only after obtaining approvals for both the medical device (ocular implant and ancillary devices) and the drug product (a customized ranibizumab 100 mg/ml formulation dedicated to the ocular implant). A regulatory filing for the drug product is planned in 2026 and is expected to include results from the domestic Phase I/II TEIEN study in patients with nAMD and DME, in addition to the Archway and Pagoda studies.

“This therapy aims to bring an entirely new treatment option to patients with nAMD and DME by leveraging an innovative ocular implant. Through a mechanism that releases the medicine at a controlled rate, the ocular implant can maintain stable drug levels in the eye over a long period. Treatment can be continued without replacing the implant, which can be refilled using a minimally invasive procedure. While the current standard of care

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

requires intravitreal injections every 4 to 16 weeks, this new approach only requires a refill-exchange once every 24 weeks, potentially reducing the physical and psychological burden associated with frequent clinic visits and procedures. We will work closely with Roche and remain fully committed to obtaining regulatory approval, with the goal of improving patients' quality of life through continued innovation in ophthalmology," said Dr. Osamu Okuda, Chugai's President and CEO.

[Reference]
Port Delivery System with Ranibizumab Demonstrates Results Phase I/II Trial for Neovascular Age-related Macular Degeneration and Diabetic Macular Edema in Japan (Press release dated November 25, 2025)
https://www.chugai-pharm.co.jp/english/news/detail/20251125153001_1204.html

About the Port Delivery Platform with ranibizumab

The Port Delivery Platform is an innovative drug delivery system, comprising an ocular implant designed for the long-term, continuous release of a drug into the eye. [1-4)] The platform includes the implant and an insertion device, as well as ancillary devices (initial fill needle, refill needle, and explant tool).

The Port Delivery Platform with ranibizumab consists of this implant in combination with a customized 100 mg/ml ranibizumab formulation.[5)] Ranibizumab is a VEGF inhibitor designed to bind to and inhibit vascular endothelial growth factor-A (VEGF-A). VEGF-A has been shown to reduce angiogenesis and vascular leakage in patients with retinal vascular diseases, including nAMD and DME.[1-3,6)] Following implantation, the refill formulation is exchanged once every 24 weeks in patients with nAMD and DME. Relative to standard-of-care intravitreal injections administered at 4- to 16-week intervals, this therapy is expected to provide sustained efficacy for approximately six months, enabling reduced dosing frequency and potentially alleviating the burden on patients, their families, and healthcare systems.

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 uncontrollably under the macula, causing fluid leakage, retinal edema, inflammation, 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)

Diabetic macular edema (DME) is estimated to affect approximately 29 million people worldwide and, if left untreated, is a vision-threatening retinal disease that may lead to blindness and reduced quality of life.[12-15)] DME is a chronic complication of diabetes caused by persistent hyperglycemia; damaged blood vessels leak into the macula, resulting in edema.[16,17)] The number of people with DME is expected to grow as the prevalence of diabetes increases.[18)]

Sources

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