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Chugai Files New Drug Application in Japan for Faricimab, the First Bispecific Antibody in Ophthalmology for Diabetic Macular Edema and Neovascular Age-related Macular Degeneration

- Chugai filed a regulatory application in Japan for faricimab as the first bispecific antibody in ophthalmology
- The application was made for diabetic macular edema and neovascular age-related macular degeneration based on two global clinical trials each

TOKYO, June 11, 2021 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that it filed a new drug application with the Ministry of Health, Labour and Welfare (MHLW) for faricimab, the anti VEGF/anti Ang-2 bispecific antibody, for the treatment of diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD) on June 10, 2021.

“DME and nAMD are major causes of blindness and vision loss in adults. The number of patients are expected to increase with the aging of the world’s population. Faricimab is the first bispecific antibody designed for the eye, and aims to provide a treatment option with a new mechanism of action for these diseases,” said Chugai’s President and CEO, Dr. Osamu Okuda. “Faricimab is the first intraocular injection to achieve treatment intervals of up to 16 weeks in multiple phase III clinical trials in DME and nAMD. It is expected to reduce the burden associated with hospital visits and treatment. In order to contribute to treatment in ophthalmology through innovation, Chugai will continue to working together with Roche to obtain regulatory approval for faricimab.”

This application is based on the results of YOSEMITE and RHINE studies in DME, and TENAYA and LUCERNE studies in nAMD. Development of faricimab in Japan is conducted by Chugai, which has been participating in YOSEMITE and TENAYA studies.

[Reference]

- YOSEMITE and RHINE studies

Roche’s faricimab meets primary endpoint and shows strong durability across two global phase III studies for diabetic macular edema, a leading cause of blindness (Press release by Roche issued on December 21, 2020)

<https://www.roche.com/media/releases/med-cor-2020-12-21.htm>

- TENAYA and LUCERNE studies

Roche’s faricimab meets primary endpoint in two global phase III studies and shows potential to extend time between treatments up to 16 weeks for people with neovascular age-related macular degeneration (Press release by Roche issued on January 25, 2021)

<https://www.roche.com/media/releases/med-cor-2021-01-25.htm>

New phase III data show Roche's faricimab is the first investigational injectable eye medicine to extend time between treatments up to four months in two leading causes of vision loss, potentially reducing treatment burden for patients (Press release by Roche issued on February 12, 2021)

<https://www.roche.com/media/releases/med-cor-2021-02-12.htm>

About faricimab

Faricimab is the first investigational bispecific antibody designed for the eye.¹⁾ It targets two distinct pathways – via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) – that drive a number of retinal conditions.²⁾ Ang-2 and VEGF-A contribute to vision loss by destabilising blood vessels, causing new leaky blood vessels to form and increasing inflammation.³⁾ By independently blocking both pathways, faricimab is designed to stabilise blood vessels, potentially resulting in better vision outcomes, for longer, for people living with retinal conditions.³⁾

About diabetic macular edema (DME)

Affecting around 21 million people globally, diabetic macular edema (DME) is a vision-threatening complication of diabetic retinopathy (DR).⁴⁾ DR occurs when damage to blood vessels and the formation of new blood vessels causes blood and/or fluid to leak into the retina – a part of the eye that sends information to the brain, enabling sight.⁵⁾ This leads to swelling, as well as blockage of blood supply to some areas of the retina.⁶⁾ DME occurs when the damaged blood vessels leak into and cause swelling in the macula – the central area of the retina responsible for the sharp vision needed for reading and driving.^{5,7)} The number of people with DME is expected to grow as the prevalence of diabetes increases.⁸⁾ The condition is associated with blindness when left untreated and decreased quality of life.^{5,9)} There remains a significant unmet need for more effective, longer-lasting therapies for people with DME.³⁾

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.¹⁰⁾ Neovascular or “wet” AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss.^{11,12)} It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.¹²⁾ 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.^{10,13,14)}

Sources

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