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Chugai Launches Vabysmo Intravitreal Injection 120 mg/mL for the Treatment of Age-related Macular Degeneration Associated with Subfoveal Choroidal Neovascularization and Diabetic Macular Edema

- Vabysmo, the first bispecific antibody in ophthalmology, has been launched for the treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema (DME)
- The bispecific antibody inhibits two disease pathways that drive neovascular age-related macular degeneration (nAMD) and DME by blocking angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A), and improves visual acuity
- Vabysmo is the first intravitreal injection to achieve 16-week dosing interval in phase III clinical trials for nAMD and DME

TOKYO, May 25, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it launched anti VEGF/anti Ang-2 bispecific antibody Vabysmo® Intravitreal Injection 120 mg/mL [generic name: faricimab (genetical recombination)] for the treatment of "age-related macular degeneration associated with subfoveal choroidal neovascularization" and "diabetic macular edema (DME)." Vabysmo had been approved by the Ministry of Health, Labour and Welfare (MHLW) on March 28, 2022 and was listed on the national health insurance (NHI) reimbursement price list today. Age-related macular degeneration associated with subfoveal choroidal neovascularization is generally known as neovascular age-related macular degeneration (nAMD).

"We are very pleased to launch Vabysmo, the first bispecific antibody in the field of ophthalmology, where Chugai will make a full-scale entry for the first time. The two diseases for which Vabysmo is indicated carry the risk of significant vision loss or blindness, if not properly treated. In addition to providing information for healthcare professionals, we will focus on supporting patients and care givers through a disease awareness website and other tools, so that Vabysmo may contribute to ophthalmic treatment." said Chugai's President and CEO, Dr. Osamu Okuda.

Vabysmo is designed to inhibit two disease pathways involved in many retinal diseases by blocking the actions of vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2 (Ang-2).[1)] This approval is based on four global phase III clinical trials (DME: YOSEMITE and RHINE studies, nAMD: TENAYA and LUCERNE studies). In these trials, Vabysmo improved visual acuity, the primary endpoint, and achieved a treatment duration of up to 16 weeks interval for the first time as an intravitreal injection in phase III clinical trials for these diseases.

Regional medical representatives (MRs) will conduct information provision activities for Vabysmo, while Specialty MRs will take over the roll after the sales reorganization planned in July. In addition,

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

ophthalmology specialist MRs have been placed to respond to the need for more specialized information, to work in cooperation with the regional MRs.

[Reference]
Ever visible.jp　a website on the pathology, diagnosis and treatment of nAMD and DME (Japanese only)
https://mieruwoitsumademo.jp (new release May 25, 2022)

Chugai Obtains Regulatory Approval for Vabysmo, the First Bispecific Antibody in Ophthalmology, for Neovascular Age-related Macular Degeneration and Diabetic Macular Edema (March 28, 2022)
https://www.chugai-pharm.co.jp/english/news/detail/20220328160002_909.html

・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

[Approval Information]
Product name: VABYSMO ® for Intravitreal Injection 120 mg/mL
Generic name: faricimab (genetical recombination)
Indications:
・ age-related macular degeneration associated with subfoveal choroidal neovascularization
・ diabetic macular edema
Dosage and administration:
< age-related macular degeneration associated with subfoveal choroidal neovascularization >
6 mg (0.05 mL) of faricimab (Genetical Recombination) is administered by intravitreal injection once every 4 weeks typically for the first four times (loading period) but number of injections can be decreased appropriately according to the patient's symptoms. In the subsequent maintenance period, it is typically administered by intravitreal injection once every 16 weeks. Dosage intervals are to be adjusted as appropriate according to the patient's symptoms, but the minimum interval is to be at least 8 weeks.
< diabetic macular edema >
6 mg (0.05 mL) of faricimab (Genetical Recombination) is administered by intravitreal injection once every 4 weeks typically for the first four times but number of injections can be decreased appropriately according to the patient's symptoms. Then, it is typically administered by intravitreal injection once every 16 weeks after gradually extending the dosing interval. Dosage intervals are to be adjusted as appropriate according to the patient's symptoms, but the intervals are to be at least 4 weeks.
Date of approval: March 28, 2022

Date of NHI reimbursement price listing: May 25, 2022
Date of launch: May 25, 2022
Drug price: Vabysmo® Intravitreal Injection 120 mg/mL JPY 163,894 / bottle

About Vabysmo (faricimab)
Vabysmo (faricimab) is the first investigational bispecific antibody designed for the eye.[4] 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.[5] Ang-2 and VEGF-A contribute to vision loss by destabilizing blood vessels, causing new leaky blood vessels to form and increasing inflammation.[3] By simultaneously blocking both pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilize blood vessels, potentially improving vision outcomes for longer for people living with retinal conditions.[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.[6] Neovascular or "wet" AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss.[7,8] It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.[8] 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.[6,9,10]

About diabetic macular edema (DME)
Affecting around 21 million people globally, diabetic macular edema (DME) is a vision-threatening complication of diabetic retinopathy (DR).[11] 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.[12] This leads to swelling, as well as blockage of blood supply to some areas of the retina.[13] 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.[12,14] The number of people with DME is expected to grow as the prevalence of diabetes increases.[15] The condition is associated with blindness when left untreated and decreased quality of life.[12,16] There remains a significant unmet need for more effective, longer-lasting therapies for people with DME.[3]

Sources
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