

# News release

## **Kyowa Kirin Announces First Patient Enrolled in the Phase 2 Clinical Trial Evaluating Tivozanib Eye Drops in Patients with Diabetic Macular Edema**

**TOKYO, February 6, 2024-** Kyowa Kirin Co., Ltd. (TSE: 4151) today announced the enrollment of the first patient in a Phase 2 clinical trial, multi-center, randomized, double-masked, parallel group study of tivozanib eye drops (KHK4951). This study investigates the efficacy and safety of KHK4951 in patients with diabetic macular edema (DME). Tivozanib, the active ingredient of KHK4951 is a small-molecule vascular endothelial growth factor receptor (VEGFR)-1, -2, and -3 tyrosine kinase inhibitor (TKI) discovered and developed by Kyowa Kirin. KHK4951 is a novel nano-crystalized tivozanib eye drops designed to deliver it efficiently to the posterior ocular tissues and is being developed as a potential treatment option for neovascular (wet) age-related macular degeneration (nAMD) and DME. An oral formulation of tivozanib is currently marketed as FOTIVDA<sup>®</sup> in the U.S. by AVEO Oncology, an LG Chem Company, and in Europe by EUSA Pharma (UK) Ltd. for another indication.

The Phase 2 study will be recruiting 150 patients with DME across the US, Japan, Australia and South Korea. The primary outcome measure is reduction of 15 or more letters from baseline in BCVA (Best Corrected Visual Acuity) as measured by the ETDRS visual acuity chart.

“Tivozanib eye drops have the potential to provide a novel non-invasive treatment option for patients with DME”, said Takeyoshi Yamashita, Ph.D., Director of the Board, chief medical officer, and senior managing executive officer of Kyowa Kirin. “The current standard of care is intravitreal injection drugs, which causes various burdens for patients, caregivers and doctors. We believe KHK4951 has the potential to address patient needs and preferences for a less invasive mode of administration.”

A separate Phase 2 study to evaluate KHK4951 in patients with neovascular(wet) age-related macular degeneration(nAMD) is also being initiated. This study is currently recruiting patients.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and

technologies.

### **About diabetic macular edema (DME)**

DME remains the most common cause of vision loss among working-age patients with diabetes mellitus and affects about 1.3 million people in the US. DME can occur at any stage of diabetic retinopathy. It is manifested as retinal thickening and swelling of the macula caused by the accumulation of intraretinal fluid, primarily in the inner and outer plexiform layers, and is believed to be a result of leakage of the retinal vasculature.

At present, the treatment choices for DME are all invasive pharmacologic therapies are intravitreal anti-VEGF or corticosteroid injections, and surgical therapies are laser photocoagulation or vitrectomy.

### **About Kyowa Kirin**

Kyowa Kirin aims to discover novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, we have invested in drug discovery and biotechnology innovation for more than 70 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by a severe or rare disease. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions – Japan, Asia Pacific, North America, and EMEA/International. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com>.