



NEWS RELEASE

Merck's Remigromig, a Tri-specific Agonist of the Wingless-related Integration Site (Wnt) Pathway, Met Primary Endpoint in the Pivotal Phase 2b/3 BRUNELLO Study of Adults with Diabetic Macular Edema

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Remigromig demonstrated non-inferiority to active control ranibizumab for mean change from baseline in best-corrected visual acuity (BCVA) at week 52

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced topline results from the pivotal Phase 2b/3 BRUNELLO trial in adults with diabetic macular edema (DME). BRUNELLO is the first of two Phase 2b/3 trials evaluating the safety and efficacy of remigromig (MK-3000, formerly EYE103), an investigational, potentially first-in-class tetravalent, tri-specific antibody designed to activate the Wingless-related integration site (Wnt) pathway, which is involved in the repair and maintenance of the blood-retinal-barrier.

At 52 weeks, both doses of remigromig (0.5 mg and 0.8 mg) independently demonstrated non-inferiority to active control 0.5 mg ranibizumab for mean change from baseline in best-corrected visual acuity (BCVA) in patients with DME. In addition, both doses of remigromig were generally well tolerated. Higher rates of proliferative diabetic retinopathy (PDR), vitreous hemorrhage, and treatment discontinuations due to adverse events were observed in the remigromig treatment arms compared with ranibizumab. Further analyses are underway to characterize these findings.

The BRUNELLO year one results will be presented at the American Academy of Ophthalmology (AAO) Annual Meeting in New Orleans, Saturday, Oct. 10, at 5:10 p.m. CT [BRUNELLO: 1-Year Pivotal Trial Results of Remigromig (MK-3000, formerly EYE103) for the Treatment of Diabetic Macular Edema; D. D'Amico] and will be discussed with regulatory authorities.

“Despite available therapies, up to 40% of patients with diabetic macular edema do not fully respond and remain at risk of continued vision loss,” said Dr. David Guyer, founder, chief executive officer and president, EyeBio, a wholly-owned subsidiary of Merck. “This is the first and only new mechanism of action in 20 years that has achieved Phase 3 results non-inferior to anti-VEGF therapy – representing an important milestone for patients in developing a potential new treatment. We look forward to sharing these findings with the scientific community at AAO.”

“We are pleased to share the first Phase 3 findings for remigromig,” said Dr. Dean Y. Li, president, Merck Research Laboratories. “We look forward to advancing remigromig in diabetic macular edema, a leading cause of vision loss for people with diabetes, with the hope of offering a new treatment option with the first novel mechanism of action for retinal vascular diseases in more than two decades.”

The BRUNELLO topline results build on Merck’s advancing ophthalmology pipeline, which is aimed at promoting retinal recovery by addressing specific retinal diseases associated with vascular leakage and neovascularization, including DME, neovascular (wet) age-related macular degeneration (NVAMD) and macular edema secondary to retinal vein occlusion (RVO). In addition to BRUNELLO, remigromig is being evaluated in the ongoing pivotal Phase 2b/3 BAROLO study (**NCT06957080**) in patients with DME and in a Phase 2 proof-of-concept study (SUPER TUSCAN) in patients with NVAMD and RVO (**NCT07205887**).

In addition, the company is developing MK-8748 (also known as Tiespectus, EYE201), a novel investigational bispecific antibody with a dual mechanism that directly activates the Tie2 pathway and inhibits VEGF with the goal of stabilizing retinal and choroidal blood vessels and reducing fluid accumulation in the macula. MK-8748 is currently being studied in two pivotal Phase 2b/3 trials for the treatment of NVAMD, TORRONTES (**NCT07496567**) and MALBEC (**NCT07440225**), and in two pivotal Phase 3 studies for the treatment of DME, SANGIOVESE (**NCT07705555**) and SYRAH (**NCT07705607**).

About the BRUNELLO trial

BRUNELLO is a randomized, double masked pivotal Phase 2b/3 trial (**NCT06571045**) evaluating the safety and efficacy of two dose levels (0.5 mg and 0.8 mg) of intravitreal (IVT) remigromig (MK-3000, formerly EYE103) versus active control 0.5mg ranibizumab in adults with DME. The trial enrolled 984 participants who were randomized 1:1:1 to receive low and high dose regimens of remigromig or ranibizumab every four weeks for the first year. In the second year, the frequency of treatment for participants will shift based on a personalized treatment interval (PTI)

algorithm. The primary endpoint is mean change in best-corrected visual acuity (BCVA) from baseline to week 52 in the study eye of the participants, using standardized Early Treatment of Diabetic Retinopathy Study (ETDRS) vision testing.

About Remigromig

Remigromig (MK-3000, formerly EYE103) is an investigational, potentially first-in-class tetravalent, tri-specific antibody designed to activate the Wingless-related integration site (Wnt) pathway, which is involved in the repair and maintenance of the blood-retinal-barrier. Remigromig is being studied in patients with certain retinal diseases including diabetic macular edema (DME) and neovascular age-related macular degeneration (NVAMD). Remigromig is administered by intravitreal injection.

About diabetic macular edema

Diabetic macular edema (DME) is a serious retinal condition and a leading cause of vision loss for people with diabetes. An estimated 1.6 million people are living with DME in the United States. DME occurs when damaged blood vessels leak into the retina, resulting in swelling in the macula, the central region of the retina crucial for precise vision necessary for everyday activities. The prevalence of DME is anticipated to rise with the increasing incidence of diabetes. While currently available treatments have helped to improve outcomes, a significant number of patients, up to 40%, do not respond or only partially respond to therapy, underscoring the need for new treatment approaches.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These

statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (<http://www.sec.gov/>).

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