



NEWS RELEASE

Merck Announces Initiation of Pivotal Phase 2b/3 Trial Evaluating MK-8748 (Tiespectus), an Investigational Bispecific Tie2 Agonist/VEGF Inhibitor, for the Treatment of Neovascular Age-Related Macular Degeneration

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RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the initiation of a pivotal Phase 2b/3 trial evaluating MK-8748 (also known as Tiespectus, EYE201), a novel investigational bispecific antibody that directly activates Tie2 signaling and inhibits vascular endothelial growth factor (VEGF), for the treatment of neovascular (wet) age-related macular degeneration (NVAMD).

The study, known as MALBEC, is the first trial of a broader late-phase development program for MK-8748, with a second study in NVAMD scheduled to begin this year ([NCT07496567](#)). The decision to advance into pivotal studies is based on results from the Phase 1/2a RIOJA trial ([NCT06664502](#)), a two-part study evaluating MK-8748 in patients with either NVAMD, macular edema secondary to branch retinal vein occlusion (BRVO) or diabetic macular edema (DME).

“Despite available therapies, many patients with neovascular age-related macular degeneration remain at risk of further vision loss due to continued vascular leakage,” said Dr. David Guyer, founder, chief executive officer and president, EyeBio, a wholly-owned subsidiary of Merck & Co., Inc., Rahway, N.J., USA. “With its differentiated dual mechanism directly agonizing Tie2 and inhibiting VEGF, MK-8748 has the potential to offer a novel approach to maintain vascular stability for patients with serious retinal diseases.”



Merck is advancing an ophthalmology pipeline aimed at addressing certain retinal diseases associated with vascular leakage and neovascularization, including NVAMD, DME and macular edema secondary to retinal vein occlusion (RVO). In addition to MK-8748, the company is developing MK-3000 (also known as Restoret, EYE103), an investigational, potentially first-in-class tetravalent, tri-specific antibody that activates the Wnt signaling pathway that is being studied in two fully enrolled, ongoing registrational Phase 2b/3 studies for the treatment of DME.

About the MALBEC trial

MALBEC is a randomized, double-masked, pivotal Phase 2b/3 trial (**NCT07440225**) evaluating the safety and efficacy of two dose levels of intravitreal (IVT) MK-8748 versus active control aflibercept 2mg. Eligible patients will be randomized 1:1:1 to receive two dose regimens of MK-8748 or aflibercept 2mg; participants will initially receive three monthly (Q4W) IVT administrations of MK-8748 or aflibercept, followed by treatments every 8 weeks (Q8W) until week 48. After week 48, participants will be treated at intervals determined based on individualized response to treatment, with the last study visit at week 96. The primary endpoint is mean change in best-corrected visual acuity (BCVA) from baseline to Year 1 in the study eye of the participants, using standardized Early Treatment of Diabetic Retinopathy Study (ETDRS) vision. For further information about the MALBEC trial, please visit www.clinicaltrials.gov.

About neovascular age-related macular degeneration

Neovascular (wet) age-related macular degeneration (NVAMD) is the most common cause of vision loss among older adults, caused by the growth of abnormal blood vessels under the retina. In the United States, it is estimated that nearly 1.5 million people are living with late-stage AMD, including NVAMD.

About MK-8748

MK-8748 (also known as Tiespectus, EYE201) is 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. Preclinical and early clinical evidence indicate that dual pathway modulation may help improve vascular stability in the retina and support vision preservation in patients with certain vascular retinal diseases. MK-8748 is currently being studied in a pivotal Phase 2b/3 trial for the treatment of NVAMD, with a second study scheduled to begin this year.

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 (www.sec.gov).

Media:

Carly Myar

carly.myar@merck.com

John Cummins

john.cummins2@merck.com

Investor:

Peter Dannenbaum

(732) 594-1579

Hayley Kasko

(732) 594-4237

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