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News Release

Not intended for U.S. and UK Media

New drug applications for asundexian accepted by U.S. Food and Drug Administration under Priority Review and by Japan's Ministry of Health, Labour and Welfare

- Regulatory submissions are based on positive data from the pivotal, global Phase III OCEANIC-STROKE study
- Despite available secondary stroke prevention strategies, approximately 1 in 10 stroke survivors worldwide will have another stroke within 1 year[1]
- The U.S. Food and Drug Administration (FDA) grants Priority Review designation for the evaluation of medicines that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition[2]

Berlin, May 19, 2026 – Bayer today announced that the U.S. Food and Drug Administration (FDA) and Japan's Ministry of Health, Labour and Welfare have accepted the company's New Drug Applications (NDA) for its investigational Factor XIa (FXIa) inhibitor, asundexian, for the prevention of ischemic stroke in patients after a non-cardioembolic ischemic stroke or transient ischemic attack (TIA). In addition, the U.S. FDA granted asundexian Priority Review designation.

Approximately 12 million people experience a stroke every year.[3] Of those who survive a stroke, approximately 1 in 10 will have another stroke within 1 year, even with available secondary stroke prevention strategies.[1]

"The acceptances of submissions in key markets represent another milestone in the development of asundexian and in our commitment to secondary stroke care. More than 90 million people worldwide are living with the consequences of a stroke, highlighting its significant impact on public health," said Christian Rommel, Ph.D., Head of Research and

Development at Bayer`s Pharmaceuticals Division. “We are collaborating with health authorities to advance the approval process.”

Bayer is continuing to submit applications for marketing authorization for asundexian to other health authorities globally. China’s Center of Drug Evaluation has also recently accepted Bayer’s marketing authorization application for asundexian and granted it Priority Review designation.

About OCEANIC-STROKE

The Phase III **OCEANIC-STROKE** study investigated the efficacy and safety of the oral Factor XIa inhibitor asundexian 50 mg once-daily compared to placebo, for prevention of ischemic stroke in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA) in combination with antiplatelet therapy. It is a multicenter, international, randomized, placebo-controlled, double-blind, parallel group and event-driven study, that randomized 12,327 participants worldwide. The primary efficacy endpoint was time to ischemic stroke; the primary safety endpoint was ISTH major bleeding. The full results from OCEANIC-STROKE have recently been published in ***The New England Journal of Medicine***.

The applications to the U.S. FDA and to Japan’s Ministry of Health, Labour and Welfare are based on positive data from the Phase III OCEANIC-STROKE study. The study found that asundexian 50 mg, significantly reduced ischemic stroke by 26 percent in patients after a non-cardioembolic ischemic stroke or high-risk TIA compared to placebo, both in combination with antiplatelet therapy, with no increase in ISTH (International Society on Thrombosis and Hemostasis) major bleeding.

About FXIa Inhibitors and Asundexian

Factor XIa (FXIa) is a protein in the blood coagulation pathway with different roles in hemostasis and thrombosis. FXIa is thought to contribute to the formation of pathological thrombus growth and vessel blockage. However, FXIa has a minor role in the formation of a hemostatic plug that seals the leak at the site of vessel injury.

Asundexian is an investigational compound and has not been approved by any health authority for use in any country for any indication.

About Bayer's Commitment in Cardiovascular and Cerebrovascular Medicine
Bayer is a leader in cardiology and is advancing a portfolio of innovative treatments in cardiovascular (CV) and cerebrovascular diseases of high unmet medical need. The company has set a clear focus on developing therapies to treat such diseases (e.g., stroke, heart failure, cardiomyopathies, and chronic kidney disease) and it is our ambition to take a leading role in the care of patients with these diseases. Bayer is actively shaping the future of cardiology and neurology with a robust and diversified pipeline, strategically positioned to address critical unmet needs and drive significant long-term value. Bayer's portfolio already includes several innovative products and compounds in various stages of preclinical and clinical development.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.

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[1] Kolmos M, Christoffersen L, Kruuse C. Recurrent Ischemic Stroke – A Systematic Review and Meta-Analysis. *J Stroke Cerebrovasc Dis.* 2021;30(8):105935.

[2] U.S. Food and Drug Administration. Priority Review. 2018. Available at: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review. Last accessed: May 2026.

[3] Feigin VL, et al. World Stroke Organization (WSO): Global Stroke Fact Sheet 2022. *Int J Stroke*. 2022;17(1):18-29.