



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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European Medicines Agency confirms asundexian marketing authorization application for assessment in secondary prevention of ischemic stroke

- This application for asundexian is the first marketing authorization application submission of a Factor XIa (FXIa) inhibitor in Europe and is based on positive data from the pivotal, global Phase III OCEANIC-STROKE study
 - With increasing prevalence of ischemic stroke and stroke-related mortality, stroke is the second leading cause of death in Europe
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Berlin, June 10, 2026 – Bayer today announced that the European Medicines Agency (EMA) has positively validated and begun assessing the company's marketing authorization application for asundexian, an oral Factor XIa (FXIa) inhibitor, in the prevention of ischemic stroke in adults after a non-cardioembolic ischemic stroke or a high-risk transient ischemic attack (TIA).

Validation of the application confirms the submission is complete and begins the EMA's centralized review procedure.

Stroke is a growing public health issue, affecting around 10 million people in Europe who are living with the consequences of stroke and more than one million people who are newly impacted each year. Globally, and in Europe, stroke is the second leading cause of death, resulting in a significant burden on healthcare systems with estimated global costs reaching 891 billion US-Dollar annually.

"Between 2010 and 2019, the prevalence of ischemic stroke and stroke-related mortality increased by 4 percent and 7 percent, respectively, across EU member states underscoring the growing burden of this disease," said Christian Rommel, Ph.D., Global Head of Research and Development at Bayer's Pharmaceuticals Division. "The

acceptance of our marketing authorization application by the EMA is a testament to our unwavering commitment to offering patients in need novel treatment options.”

Bayer is continuing to submit applications for marketing authorization for asundexian to other health authorities globally. China’s Center of Drug Evaluation and the U.S. Food and Drug Administration (FDA) have recently granted asundexian 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 been published in *[The New England Journal of Medicine](#)*.

The application to the European Medicines Agency is 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.

Contact for global media inquiries:

Anne Jorgal, phone +49 30 2215-41592

Email: anne.jorgal@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/de/investoren/ir-team

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