



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

News Release

Not intended for UK Media

Bayer's Asundexian Met Primary Efficacy and Safety Endpoints in Landmark Phase III OCEANIC-STROKE Study in Secondary Stroke Prevention

- OCEANIC-STROKE demonstrates superiority of asundexian with antiplatelet therapy, showing significant reduction in ischemic stroke risk, without increasing ISTH major bleeding rate, compared to placebo with antiplatelet therapy
 - OCEANIC-STROKE is the first successfully completed Phase III study of a Factor XIa inhibitor
 - Bayer will globally engage with health authorities in preparation for the submission of marketing authorization applications and looks forward to presenting the results at an upcoming scientific congress
-

Berlin, November 23, 2025 – Bayer today announced positive topline results from the global Phase III study OCEANIC-STROKE, with its investigational, once daily, oral FXIa inhibitor asundexian. The study met its primary efficacy and safety endpoints. Asundexian 50 mg once daily significantly reduced the risk of ischemic stroke compared to placebo, both in combination with antiplatelet therapy, in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack. There was no increase in the risk of ISTH major bleeding in patients treated with asundexian compared to placebo, both in combination with antiplatelet therapy. Detailed results of OCEANIC-STROKE will be presented at an upcoming scientific congress.

Each year, approximately 12 million people worldwide will experience a stroke. Of these, 20-30% will be a recurrent stroke.^{1,2} Despite available secondary stroke prevention options, the risk of secondary stroke remains high. One in five stroke survivors will have another stroke within five years.³ Stroke is the second leading cause of death globally, and recurrent ischemic strokes tend to be more disabling and carry a higher mortality risk than the first stroke.^{2,4,5}

“As clinicians, we see every day how devastating a recurrent stroke can be for patients and their families²,” said Mike Sharma, MD, principal investigator of the Population Health Research Institute (PHRI) OCEANIC-STROKE study, Senior Scientist at PHRI (a joint institute of McMaster University and Hamilton Health Sciences), Director of the Stroke Program at Hamilton Health Sciences, and Michael G. DeGroote Chair in Stroke Prevention at McMaster University. “Even with currently available therapies, the risk of another stroke remains high, and each recurrence can have profound consequences. The topline results from OCEANIC-STROKE indicate that asundexian may become a new treatment option to reduce this risk – representing a potential major step forward in secondary stroke prevention.”

“We are excited by these positive topline findings which highlight the potential of Factor XIa inhibition as a new way to help protect patients from a recurrent stroke,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “This marks an important milestone in Bayer’s longstanding commitment to advancing innovation in thrombosis prevention. We extend our sincere gratitude to the investigators, patients, and colleagues whose dedication made this milestone possible.”

Asundexian has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) as a potential treatment for stroke prevention in patients after a non-cardioembolic ischemic stroke. Asundexian is an investigational compound and has not been approved by any health authority for use in any country for any indication.

About OCEANIC-STROKE

The [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 has enrolled over 12,300 patients. The main study results will be presented at an upcoming scientific congress.

About FXIa inhibitors and Asundexian

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

the formation of pathological thrombus growth and vessel blockage. Asundexian, a direct inhibitor of FXIa, is theorized to reduce thrombus formation that can lead to vessel stenosis or blockage, without a significant increase in major bleeding. Asundexian is currently being evaluated as a potential treatment option in thrombosis prevention. Asundexian is a once-daily, oral investigational agent and has not been approved by any health authority for use in any country, for any indication.

About Bayer's Commitment in Cardiovascular Diseases

Bayer is a leader in cardiology and is advancing a portfolio of innovative treatments in cardiovascular (CV) diseases of high unmet medical need. We have set a clear focus on developing innovative therapies to treat cardiovascular 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. Our strategy is to unlock the strong potential of the future CV market by transforming Bayer's portfolio into precision cardiology, addressing the high CV disease burden, and driving the long-term growth. 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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

Contact for 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/en/investors/ir-team

Find more information at <https://pharma.bayer.com/>

Follow us on Facebook: <http://www.facebook.com/bayer>

Follow us on LinkedIn: [Bayer | Pharmaceuticals](#)

aj (2025-0215)

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.

References:

1. Feigin VL, et al. World Stroke Organization (WSO): global stroke fact sheet 2022. *International Journal of Stroke*. 2022 Jan;17(1):18-29.
2. Feigin VL, et al. Pragmatic Solutions to Reduce Global Burden of Stroke. *Lancet Neurol*. 2023;22:1160–1206.
3. Kolmos M, et al. Recurrent ischemic stroke—a systematic review and meta-analysis. *Journal of Stroke and Cerebrovascular Diseases*. 2021 Aug 1;30(8):105935.
4. Rochmah TN, et al. Economic burden of stroke disease: a systematic review. *International journal of environmental research and public health*. 2021 Jul 15;18(14):7552.
5. Skajaa N, et al. Risks of stroke recurrence and mortality after first and recurrent strokes in Denmark: a nationwide registry study. *Neurology*. 2022 Jan 25;98(4):e329-42.