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News Release

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International Stroke Conference (ISC) 2026:

Bayer's asundexian demonstrated a substantial, 26 percent reduction in stroke after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack with no increase in ISTH major bleeding versus placebo

- In OCEANIC-STROKE, patients who received asundexian after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack were significantly less likely to suffer a secondary stroke compared to placebo, when both were combined with antiplatelet therapy
- These results were consistent across all clinically relevant patient subgroups regardless of key patient characteristics like age or sex, the cause of stroke or the severity of the stroke
- There was no increase in ISTH major bleeding, and the bleeding risk was similar to placebo for minor bleeding, hemorrhagic stroke, symptomatic intracranial hemorrhage and fatal bleeding
- OCEANIC-STROKE enrolled 12,327 patients and is the first successfully completed Phase III trial of a FXIa inhibitor which demonstrated superiority in reducing recurrent ischemic stroke compared to placebo

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New Orleans, USA, February 5, 2026 – Bayer today presented the results from the global, pivotal Phase III OCEANIC-STROKE study evaluating the use of its investigational, once-daily, oral, Factor XIa inhibitor asundexian (50mg) compared to placebo, both in combination with antiplatelet therapy. Asundexian significantly reduced ischemic stroke by 26 percent (csHR 0.74; 95% CI 0.65–0.84; p<.0001), in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack, with no increase in the risk of ISTH (International Society on Thrombosis and Hemostasis) major bleeding. These findings were consistent regardless of age or sex, index event (stroke or high-risk

TIA), stroke subtype, NIHSS (National Institutes of Health Stroke Scale), and acute stroke therapy like thrombolysis or planned secondary prevention strategies single antiplatelet therapy (SAPT) or dual antiplatelet therapy (DAPT). The results were presented at the International Stroke Conference 2026 in New Orleans, LA, USA. OCEANIC-STROKE is the first successfully completed Phase III study of a Factor XIa inhibitor which demonstrated superiority in reducing recurrent ischemic stroke compared to placebo.

“A stroke is a life-changing event for patients and a major public health burden. The findings from OCEANIC-STROKE are a notable research achievement, demonstrating a substantial reduction in the risk of stroke with asundexian compared to placebo, alongside a sustained treatment effect and a safety profile with no observed increase in ISTH major bleeding,” said Mike Sharma, Principal Investigator of the OCEANIC-STROKE study, Michael G. DeGroote Chair in Stroke Prevention, McMaster University and Senior Scientist at Population Health Research Institute, a joint institute of McMaster University and Hamilton Health Sciences. “For clinicians and researchers who have spent decades working to reduce the global burden of secondary stroke, the OCEANIC-STROKE results represent the kind of scientific progress the field has long been striving to achieve.”

Alongside the primary findings, secondary endpoints showed asundexian reduced the risk of a stroke of any kind (ischemic and hemorrhagic) by 26 percent (6.6% vs. 8.8%; csHR 0.74; 95% CI, 0.65–0.84; p<.0001) compared to placebo. In addition, the following secondary efficacy endpoints were met for asundexian compared to placebo, when both were given in combination with antiplatelet therapy: the composite endpoint of cardiovascular death, myocardial infarction (MI) or stroke, and the composite of death from any cause, MI or stroke.

The analysis of the primary safety endpoint showed that there was no increase in the rate of ISTH major bleeding with asundexian compared to placebo (1.9% vs. 1.7%; HR 1.10; 95% CI, 0.85–1.44). For the pre-specified secondary safety endpoints, the risk of bleeding was similar compared to the rates seen in the placebo-arm.

OCEANIC-STROKE enrolled all common stroke subtypes in its design, classified by the TOAST (Trial of Org 10172 in Acute Stroke Treatment) criteria. Among patients with an index ischemic stroke, the study enrolled patients with large-artery atherosclerosis (43 percent), small-vessel occlusion (lacune) (23 percent), stroke of undetermined etiology (30 percent), other determined etiology (3 percent), and cardioembolic stroke (2 percent).

Across all TOAST subtypes evaluated, rates of recurrent ischemic stroke were lower with asundexian compared with placebo.

“The consistent reduction in secondary events with asundexian across all types of strokes included in the trial, is particularly striking” said Ashkan Shoamanesh, Co-Principal Investigator of OCEANIC-STROKE study and PHRI senior scientist. “OCEANIC-STROKE was deliberately designed with the goal of making the findings generalizable to the many ways stroke presents in clinical practice. These results provide confidence that, if approved, asundexian could become an important option for secondary stroke prevention across a broad range of stroke patients.”

Each year, approximately 12 million people worldwide will experience a stroke. Of these, 20-30 percent 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]

“Stroke is a public health crisis and with the groundbreaking results of OCEANIC-STROKE, I believe Asundexian can contribute meaningfully to improve life for patients and care partners, delivering positive impact to health systems worldwide,” said Christian Rommel, Ph.D., Global Head of Research and Development, Bayer Pharmaceuticals. “We would like to offer our sincere appreciation to investigators and patients who participated in this study and look forward to discuss the results with regulatory authorities as a next step.”

Bayer will submit the data from OCEANIC-STROKE to health authorities for approval of marketing authorizations of asundexian. The compound 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 randomized 12,327 participants worldwide. The primary endpoint was time to ischemic stroke; the primary safety endpoint was 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 has a minor role in the formation of a hemostatic plug that seals the leak at the site of vessel injury.

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 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 innovative 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 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.

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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.

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.