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News Release

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Asundexian OCEANIC-STROKE Phase III study results demonstrating substantial reduction in ischemic stroke with no increase in ISTH major bleeding versus placebo published in New England Journal of Medicine

- Asundexian demonstrated a substantial 26 percent reduction in ischemic stroke after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack with no increase in ISTH major bleeding versus placebo, when both were combined with antiplatelet therapy
 - Full manuscript includes additional data on the overall net clinical benefit and safety findings of asundexian compared to placebo, when combined with antiplatelet therapy
 - OCEANIC-STROKE is the first successfully completed Phase III study of a Factor XIa inhibitor demonstrating superiority in reducing ischemic stroke compared to placebo, when both were combined with antiplatelet therapy
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Berlin, April 16, 2026 – Bayer today announced the publication of the full results from the global, pivotal Phase III OCEANIC-STROKE study in [The New England Journal of Medicine](#).¹ The study evaluated asundexian (50 mg), an investigational, once-daily, oral Factor XIa (FXIa) inhibitor, compared to placebo, both in combination with antiplatelet therapy, for the prevention of ischemic stroke in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA).

"The full published findings of OCEANIC-STROKE in the New England Journal of Medicine provide the global stroke community with a clearer understanding of the favorable net clinical benefit observed with asundexian across a broad and representative patient population," 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. “The depth of evidence from OCEANIC-STROKE will be of significant relevance in the evolution of secondary stroke prevention.”

The peer-reviewed publication expands on data presented at this year’s American Heart Association’s International Stroke Conference 2026 in New Orleans, U.S, which showed that asundexian significantly reduced ischemic stroke by 26 percent (cSHR 0.74; 95% CI 0.65 to 0.84; $p < 0.001$), 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 NEJM publication includes the positive results of three net clinical benefit outcomes, which show that asundexian reduced the composite of ischemic stroke or ISTH major bleeding, the composite of cardiovascular death, all stroke, myocardial infarction, or ISTH major bleeding and the composite of all-cause mortality, disabling stroke, fatal bleeding, or symptomatic intracranial hemorrhage compared to placebo, both in combination with antiplatelet therapy.

"This foundational body of scientific evidence reflects our continued commitment to address high unmet medical needs," said Christian Rommel, Ph.D., Global Head of Research and Development, Bayer Pharmaceuticals. "It is a remarkable contribution to clinical research of secondary stroke prevention."

Each year, approximately 12 million people worldwide experience a stroke.² Of these 20-30 percent will be a recurrent stroke.³ Despite available secondary stroke prevention options, the risk of secondary stroke remains high. Approximately one in five stroke survivors will have another stroke within five years.⁴ 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.^{3,5,6}

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 efficacy endpoint was time to ischemic stroke; the primary safety endpoint was ISTH 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 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 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 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.

References

¹ <https://doi.org/10.1056/NEJMoa2513880>

² Feigin VL, et al. World Stroke Organization (WSO): global stroke fact sheet 2022. International Journal of Stroke. 2022 Jan;17(1):18-29.

³ Feigin VL, et al. Pragmatic Solutions to Reduce Global Burden of Stroke. Lancet Neurol. 2023;22:1160–1206.

⁴ 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.

⁵ 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.

⁶ 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.