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News Release

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China's Center of Drug Evaluation accepts marketing authorization application for Bayer's FXIa inhibitor in stroke prevention after a non-cardioembolic ischemic stroke or transient ischemic attack

- The marketing authorization application for asundexian is based on positive data from the pivotal, global Phase III OCEANIC-STROKE study presented at the International Stroke Conference 2026
- Each year, approximately 12 million people worldwide will experience a stroke, making it the leading cause of death and disability in China[1]

Berlin, April 29, 2026 – Bayer today announced that the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has accepted the company's marketing authorization application for asundexian as a treatment for the prevention of ischemic stroke in patients after a non-cardioembolic ischemic stroke or transient ischemic attack (TIA).

Stroke is the second-leading cause of death and the third-leading cause of disability globally. While in China it is the leading cause of death and disability.[1,2] The prevalence of ischemic stroke in China increased by 10% between 2010 and 2021 to 20.80 million ischemic stroke cases.[1] Recurrent ischemic strokes tend to be more disabling and carry a higher mortality risk than the first stroke.[2,3,4]

"The acceptance of our marketing authorization application marks a significant milestone in our efforts to advance secondary stroke prevention in China, where the burden of stroke is substantial and a need for additional options in secondary stroke prevention remains," said Christian Rommel, Ph.D., Global Head of Research and Development, Bayer Pharmaceuticals.

The marketing authorization application to the CDE is based on positive data from the Phase III OCEANIC-STROKE study, which showed that asundexian significantly reduced ischemic stroke by 26 percent compared to placebo, both in combination with antiplatelet therapy, in patients after a non-cardioembolic ischemic stroke or high-risk TIA, with no increase in 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 or dual antiplatelet therapy).

Bayer is continuing to submit applications for marketing authorizations of asundexian to health authorities globally.

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 recently been published in ***The New England Journal of Medicine***, 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 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.

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[1] National Program for Stroke Prevention and Million Disability Reduction Initiative Expert Committee. China Stroke Prevention and Control Report 2024: An executive summary. *Brain Circ*. 2025;11(4):251-260.
[2] Feigin VL, et al. Pragmatic Solutions to Reduce Global Burden of Stroke. *Lancet Neurol*. 2023;22:1160–1206.
[3] Rochmah TN, et al. Economic Burden of Stroke Disease: A Systematic Review. *Int J Environ Res Public Health*. 2021;18(14):7552.
[4] Skajaa N, et al. Risks of stroke recurrence and mortality after first and recurrent strokes in Denmark: a nationwide registry study. *Neurology*. 2022;98(4):e329-42.