



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

News Release

Not intended for U.S. and UK Media

Asundexian first Factor Xla inhibitor approved in China for stroke risk reduction after priority review

- With this approval, asundexian will become the first Factor Xla inhibitor (FXIa) available in China, to reduce the risk of stroke in adults after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack
 - Regulatory approval follows the China's Center of Drug Evaluation's Priority Review designation and is based on positive data from the pivotal, global Phase III OCEANIC-STROKE study
 - Stroke is the leading cause of death and disability in China
-

Berlin, October 26 2026 – Bayer announced today that China's National Medical Products Administration (NMPA) has granted marketing authorization for asundexian, under the brand name Sunharbo®. Asundexian, 50 mg, a selective, once-daily oral Factor Xla inhibitor (FXIa), is indicated to reduce the risk of stroke in adults after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA). Sunharbo® (asundexian) is the first FXIa inhibitor approved worldwide.

In China, stroke is the leading cause of death and disability. Between 2010 and 2021, the prevalence of ischemic stroke increased by 10% to more than 20 million ischemic stroke cases in China. Globally, approximately 1 in 10 non-cardioembolic ischemic stroke survivors experience another stroke within one year, even with available secondary stroke prevention strategies.

"With the approval of asundexian, we have reached an important milestone and are proud soon to be able to offer physicians in China a new treatment option for stroke survivors after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack. This enables us to address an unmet need with limited therapeutic advances over the past two decades," said Christian Rommel, Ph.D., Global Head of Research and Development at

Bayer's Pharmaceuticals Division. "We are working with stakeholders and medical communities to support equitable and timely access for eligible patients in China."

Asundexian has been submitted for marketing authorization in additional markets around the world. These applications are currently under review, while Bayer continues to work with health authorities worldwide to bring asundexian to patients in other regions.

Key Clinical Trial Findings Supporting Approval

The approval by China's National Medical Products Administration (NMPA) is based on positive data from the pivotal, global Phase III OCEANIC-STROKE study, the first successfully completed Phase III study of a Factor Xla inhibitor in combination with dual antiplatelet therapy (DAPT) / single antiplatelet therapy (SAPT) demonstrating superiority in reducing ischemic stroke, compared to DAPT/SAPT alone. The incidence of all bleeding events was similar between the two treatment groups, in patients after a non-cardioembolic stroke or high-risk TIA. Key findings demonstrated:

- Asundexian 50 mg in combination with DAPT/SAPT, significantly reduced ischemic stroke by 26% in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA), compared to DAPT/SAPT alone.
- The incidence of all bleeding events was similar between the two treatment groups.
- Treatment effect for the primary endpoint was consistent across key subgroups (including age, sex, type of index event, non-cardioembolic stroke subtypes, stroke severity, and planned antiplatelet therapy) supporting its potential use across a broad patient population.
- The full results from OCEANIC-STROKE have been published in [*The New England Journal of Medicine*](#)

About OCEANIC-STROKE

The Phase III **OCEANIC-STROKE** study investigated the efficacy and safety of the selective, once-daily oral Factor Xla inhibitor asundexian 50 mg in combination with DAPT/SAPT, compared to DAPT/SAPT alone, for risk reduction of ischemic stroke in patients after a non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA). OCEANIC-STROKE 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 (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 the first approved FXIa inhibitor worldwide. It selectively inhibits FXIa, allowing to reduce pathological clot formation, with similar incidence of all bleeding events between the two treatment groups, by uncoupling hemostasis from pathological thrombosis.

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 support efforts to master major challenges presented by a growing and aging global population 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:

Astrid Kranz, phone +49-30-2215-41596

Email: astrid.kranz@bayer.com

Jutta Schulze, phone +49 175 30 02905

Email: jutta.schulze@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 (2026-0184e)

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.