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News Release

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New asundexian Phase III study to include patients with atrial fibrillation ineligible for oral anticoagulant treatment

- New study includes patients aged ≥65 years with atrial fibrillation (AF) at high risk for ischemic stroke or systemic embolism who are deemed ineligible for oral anticoagulant (OAC) treatment due to increased risk of bleeding
- OCEANIC-AFINA, the latest Phase III study in the OCEANIC clinical trial program, will investigate asundexian in this specific patient group
- OCEANIC-AFINA complements the ongoing OCEANIC-AF study, further expanding Bayer's landmark clinical trial program with asundexian, enrolling nearly 30,000 patients in over 40 countries
- Asundexian is being evaluated as a treatment option in stroke prevention and is part of an entirely new class of treatment options in thrombosis management

Berlin, November 6, 2023 – Bayer expands its Phase III OCEANIC clinical development program for the investigational drug asundexian (BAY2433334) by initiating a third clinical study, OCEANIC-AFINA. OCEANIC AFINA is a Phase III study investigating asundexian as a potential treatment in patients (≥65 years of age) with atrial fibrillation (AF) at high risk for stroke or systemic embolism who are deemed ineligible for oral anticoagulation (OAC) treatment due to an increased risk of bleeding. OCEANIC-AFINA complements OCEANIC-AF, an ongoing Phase III study investigating the efficacy and safety of asundexian for the prevention of stroke or systemic embolism in people with AF at risk of stroke. Together, the results from OCEANIC-AFINA and OCEANIC-AF aim at providing robust evidence for the efficacy and safety of asundexian across a broad range of patients with AF, including those who are at high risk for both ischemic stroke or systemic embolism and major bleeding events.

Studies show that 1 in 3 patients with atrial fibrillation are undertreated or untreated with oral anticoagulants, leading to a substantial unmet need for an effective therapy that does

not further increase the risk of bleeding during treatment. Elderly patients with AF at high risk for bleeding and patients with AF and end-stage kidney disease (ESKD) on hemodialysis are often treated with a lower dose than recommended by guidelines. Further, those who discontinue OACs are at increased risk of experiencing a subsequent ischemic stroke. Inhibiting FXIa with asundexian might be able to tackle this unmet need, as it could provide protection from thrombotic events without a corresponding increase in bleeding risk.

“The promising clinical results we have seen so far indicate that asundexian could mark a new option for antithrombotic treatment for a broader range of patients”, said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. “It is our vision to support patients with atrial fibrillation, including those, that up to now were deemed as not eligible for treatment with OACs. We aim to offer them a new therapy option to improve their quality of life by reducing the fear of potential increased bleeding and help physicians confidently prescribe antithrombotic treatment to protect their patients. With OCEANIC-AFINA we will evaluate asundexian in a vulnerable untreated patient population.”

“For physicians, there are challenging clinical decisions we have to make when considering treatment options for atrial fibrillation patients who are at high bleeding risk, and not suitable for currently available oral anticoagulants”, said Dr. Roxana Mehran, Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at Icahn School at Mount Sinai. “These patients are often overlooked and excluded from clinical trial, so it is gratifying to see Bayer’s announcement of this study.”

OCEANIC-AFINA is a multicenter, international, randomized, placebo-controlled, double-blind, parallel-group, 2-arm Phase III study comparing the use of asundexian with placebo in patients (≥65 years of age) with AF at high risk for stroke or systemic embolism who are deemed ineligible to receive treatment with OACs. The primary efficacy objective of OCEANIC-AFINA is to compare the time to first occurrence of ischemic stroke or systemic embolism between AF patients treated with asundexian or placebo. The primary safety objective is to describe the time to first occurrence of ISTH (International Society on Thrombosis and Hemostasis) major bleeding in participants receiving asundexian and placebo. The study is expected to enroll nearly 2,000 patients with AF.

Asundexian is an investigational agent and has not been approved by any health authority for use in any country, for any indication. It is currently being evaluated as a potential once-daily oral Factor XIa (FXIa) inhibitor for prevention of thromboembolic events, reducing pathological clot formation while allowing hemostasis to form clots to stop the bleeding.

About the OCEANIC Program

The OCEANIC clinical trial program is designed to evaluate the use of asundexian, as an oral FXIa inhibitor, in patients with atrial fibrillation (AF) at risk of stroke and in patients following acute non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA), aiming to improve the benefit-risk profile when compared to standard of care. The program started with two large multinational studies, OCEANIC-AF and OCEANIC-STROKE, and is one of the largest clinical trial programs Bayer has undertaken, expecting to enroll nearly 30,000 patients in over 40 countries.

The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for asundexian as a potential treatment to prevent stroke and systemic embolism in people with atrial fibrillation (AF) as well as for the prevention of stroke in patients after an acute non-cardioembolic ischemic stroke.

About OCEANIC-AF, OCEANIC-STROKE and OCEANIC-AFINA

OCEANIC-AF is a multicenter, international, randomized, active comparator-controlled, double-blind, double-dummy, parallel-group, 2-arm Phase III study investigating asundexian compared to apixaban (a non-vitamin K antagonist oral anticoagulant) in patients with atrial fibrillation at risk for stroke to determine the safety and efficacy of asundexian on prevention of stroke and systemic embolism.

OCEANIC-STROKE is a multicenter, international, randomized, placebo-controlled, double-blind, parallel group and event-driven Phase III study investigating the efficacy and safety of asundexian for prevention of ischemic stroke compared to placebo on top of standard-of-care antiplatelet therapy in patients after an acute non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA) / mini-stroke.

OCEANIC-AFINA is a multicenter, international, randomized, placebo-controlled, double-blind, parallel-group, 2-arm Phase III study comparing the use of asundexian with placebo

in patients with atrial fibrillation (AF) (≥65 years of age) at high risk for stroke or systemic embolism who are deemed ineligible for OAC treatment.

About FXIa inhibitors and Asundexian

Factor XI is a protein in the blood which is converted into its active enzyme form (Factor XIa) as part of the blood coagulation cascade. FXIa inhibition specifically targets the FXIa protein involved in pathological thrombus formation, while leaving hemostasis intact. Asundexian, as an oral direct, potent inhibitor of activated coagulation factor XI (FXIa), acts selectively on the coagulation cascade, thereby offering the potential to prevent events like stroke without a corresponding increase in bleeding risk associated with the current standard of care (SoC). Asundexian is currently being evaluated as a potential treatment option in thrombosis prevention and could represent a new approach in antithrombotic treatment. 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 Atrial Fibrillation

AF is one of the most common sustained cardiac rhythm disorders (arrhythmias). It results from rapid, disorganized electrical signals in the upper chambers (atria) of the heart, causing them to quiver and contract quickly and irregularly. As a result, the atria do not empty completely, and blood does not flow properly, causing blood clots to form. These blood clots can break loose and travel to the brain, resulting in a stroke.

About Bayer

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Forward-Looking Statements
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