Bayer Receives U.S. FDA Fast Track Designation for asundexian Stroke Program

Berlin, February 10, 2022 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its investigational drug asundexian (BAY2433334) as a potential treatment for secondary prevention in patients with a non-cardioembolic ischemic stroke.

Asundexian is an oral inhibitor of Factor Xla (FXla) that Bayer is developing as a potential treatment for secondary prevention in patients with a non-cardioembolic ischemic stroke as well as for two additional conditions: atrial fibrillation (irregular heartbeat) and recent myocardial infarction (heart attack). Asundexian is currently in Phase II clinical trials in all three indications either as a standalone therapy, or in combination with anti-platelet therapy. Inhibition of FXIa by asundexian is hypothesized to provide protection from thrombotic events without increasing the risk of bleeding.

Fast Track Designation is intended to facilitate the development and expedite the review of drug candidates to treat serious medical conditions and fulfill unmet medical needs. The purpose of the program is to get important new therapeutics to the patient earlier. A drug candidate that receives Fast Track Designation may be eligible for more frequent interactions with the U.S. FDA to discuss the drug candidate’s development plan and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

About Asundexian and FXIa Inhibitors
Asundexian (BAY2433334) is an oral Factor Xla (FXla) inhibitor (anti-thrombotic) and is part of a portfolio of assets targeting FXI or FXIa inhibitors currently in clinical development by Bayer. Asundexian is currently being studied in the PACIFIC Phase II clinical trial program that consists of three Phase IIb studies in over 4,000 patients with one of the following three medical conditions: atrial fibrillation (irregular heartbeat), a
recent non-cardioembolic ischemic stroke or a recent myocardial infarction (heart attack). By specifically targeting a protein involved in pathological thrombus formation, but leaving the pathway involved in physiological vessel healing intact, FXIa inhibitors could have the potential to prevent events like stroke and myocardial infarction (MI) without a corresponding increase in bleeding risk. This program is designed to provide further support for the hypothesis that inhibiting FXIa with asundexian can reduce the risk of thrombotic events without increasing the risk of bleeding. Asundexian is an investigational agent and has not been approved by any health authority for use in any country, for any indication.

More information about these trials is available at clinicaltrials.gov. The National Clinical Trial numbers for these studies are PACIFIC-AF (atrial fibrillation) NCT04218266, PACIFIC-STROKE (non-cardioembolic ischemic stroke) NCT04304508 and PACIFIC-AMI (myocardial infarction) NCT04304534.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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