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

News Release

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Phase 2b studies of investigational selective coagulation modulators fesomersen and osocimab in patients with advanced renal disease completed

Berlin, Germany, July 28, 2022 – Bayer today announced completion of two Phase 2b clinical trials: the RE-THINC ESRD trial and the CONVERT trial. The RE-THINC ESRD trial evaluated the safety of fesomersen, Bayer's investigational, subcutaneously administered ligand-conjugated antisense (LICA) oligonucleotide, in patients with end-stage renal disease (ESRD) on hemodialysis. The CONVERT trial evaluated the safety and tolerability of osocimab, Bayer's investigational, subcutaneously administered human monoclonal IgG1 antibody in patients with ESRD on hemodialysis.

The data from both trials will be presented at an upcoming scientific meeting.

Fesomersen and osocimab are investigational agents and have not been approved for use in any country, for any indication. Fesomersen was discovered and initially developed by Ionis Pharmaceuticals, Inc. who has granted Bayer an exclusive license to further develop and commercialize the compound.

About the RE-THINC ESRD Phase 2b Trial: The RE-THINC ESRD trial is a Phase 2, randomized, double-blinded, placebo-controlled study of the safety, pharmacokinetics, and pharmacodynamics of multiple doses of fesomersen in patients with end-stage renal disease (ESRD) on hemodialysis. Patients with ESRD are at high risk for blood clots that form in blood vessels (thrombosis) blocking blood flow and which, in turn, can cause heart attacks, strokes, and other life-threatening conditions, as well as at high risk of bleeding, even when not treated with any anti-thrombotic. More information about this trial is available at www.clinicaltrials.gov. The National Clinical Trial number for this study is NCT04534114.

About fesomersen: Fesomersen, formerly known as IONIS-FXI-LRx, is an investigational ligand-conjugated antisense (LICA) oligonucleotide designed to reduce the production of Factor XI (FXI), a clotting factor produced in the liver that is an important component of the coagulation pathway. By specifically targeting a protein involved in pathological thrombus formation but leaving the pathway involved in physiological vessel healing intact, fesomersen is being investigated for its potential to prevent thrombo-embolic events without a corresponding increase in bleeding risk. Fesomersen is administered as a monthly subcutaneous injection and was discovered and initially developed by Ionis Pharmaceuticals, Inc.

About antisense technology: Antisense technology uses short fragments of synthesized nucleic acids (oligonucleotides), which are complementary to the messenger RNA (mRNA) of a targeted gene. Antisense oligonucleotides (ASOs) bind to the messenger RNA of a targeted molecule and modulate its function. In the case of FXI ASO, binding to FXI mRNA inhibits the hepatic synthesis of FXI. ASOs are administered subcutaneously at a frequency of weekly to monthly.

About the CONVERT Phase 2b Trial: The CONVERT trial is a randomized, double-blind, placebo-controlled Phase 2 dose-finding study, comparing two different dosing regimens of osocimab (high-dose: 210 mg loading dose followed by monthly maintenance doses of 105 mg or low-dose: 105 mg loading dose combined with 52.5 mg maintenance dose) with placebo in end-stage renal disease (ESRD) patients, who are stable on hemodialysis/hemodiafiltration. The primary endpoints are the composite of major and clinically relevant non-major bleeding and the composite of moderate and severe adverse events. CONVERT is the first multiple dose study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of the subcutaneous formulation of the investigational drug in this patient population. Currently, there is no approved anticoagulant treatment available for the effective prevention of thromboembolic events in patients with ESRD on a regular hemodialysis/hemodiafiltration program. More information about this trial is available at www.clinicaltrials.gov. The National Clinical Trial number for this study is NCT04523220.

About Osocimab: Osocimab (BAY 1213790) is a fully human monoclonal IgG1 antibody that specifically binds to the activated factor XI (FXIa). By binding adjacent to the active site of FXIa, the antibody modifies the ability of FXIa to bind to natural substrates, thereby

preventing the propagation of the thrombotic cascade and ultimately aiding in the formation and stabilization of blood clots.

About end-stage renal disease: End-stage renal disease (ESRD), also known as end-stage kidney disease (ESKD), is a medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. Numerous medical conditions may cause ESRD, one of the most common being atherosclerotic vascular disease driven by diabetes and/or high blood pressure. ESRD patients requiring regular hemodialysis are at increased risk for fatal and non-fatal cardiovascular complications (stroke, heart attack, systemic embolism, etc.) which may necessitate preventive anticoagulant therapy. However, ESRD patients on hemodialysis also have an increased risk for major bleedings due to frequent issues with thrombocytopenia, anemia, heparin use and comorbidities. This predisposition limits the use of currently available anticoagulants, such as vitamin K antagonists or non-vitamin K antagonist oral anticoagulants, and highlights the need for coagulation modulators that do not pose additional risk for bleeding.

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 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 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:
Pamela Cohen, phone + 49 30 2215-41587
Email: pamela.cohen@bayer.com

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Forward-Looking Statements
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