News Release

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Milvexian Granted U.S. FDA Fast Track Designation for All Three Indications Under Evaluation in Phase 3 Librexia Program: Ischemic Stroke, Acute Coronary Syndrome and Atrial Fibrillation

The Librexia program evaluating milvexian is unrivaled as the most comprehensive factor XIa inhibitor clinical development program to date and will provide extensive data from nearly 50,000 patients, with all three studies underway

RARITAN, NJ, May 25, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that all three prospective indications for milvexian, an investigational oral factor XIa (FXIa) inhibitor (being developed in collaboration with Bristol Myers Squibb), have now been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA). The designations cover all three indication-seeking studies within the Phase 3 Librexia development program (Librexia STROKE, Librexia ACS and Librexia AF), which are all dosing patients. The Librexia program is unrivaled as the most comprehensive FXIa clinical development program to date and will provide extensive data from nearly 50,000 patients.

"Despite major advances in cardiovascular and stroke treatment over the past two decades, millions of patients currently remain untreated or undertreated due to the

risk of bleeding, but for whom thrombotic events could be prevented," said Robert Harrington, M.D., Arthur L. Bloomfield professor of medicine and chair of the Department of Medicine, Stanford University, Librexia program chair.[i] "If successful, milvexian could open the door to treat an entirely new set of patients who are currently overlooked due to bleeding risk."

All three indications being studied in the Phase 3 Librexia program were granted Fast Track Designation from the FDA. Fast Track Designation is intended to expedite development and review timelines when preliminary nonclinical and clinical evidence indicates the drug may demonstrate substantial improvement over available therapies to address unmet medical need for serious or life-threatening conditions. Fast Track Designation encourages close communication between the FDA and sponsor to improve the efficiency of product development, with the aim of getting new therapeutics to patients faster.

"For milvexian to receive Fast Track Designation from the FDA for all three indications demonstrates the enormous unmet need that still exists for the treatment of thrombotic events, like heart attack and stroke," said James F. List, M.D., Ph.D., Global Therapeutic Area Head, whose team oversees a portfolio of programs, including milvexian, at Janssen Research & Development, LLC. "We are now focused on enrolling patients to these trials with urgency, bringing us one step closer to potentially improving outcomes in a wide range of patients with thrombotic diseases."

Phase 2 AXIOMATIC-TKR and AXIOMATIC-SSP proof-of-concept data for milvexian demonstrated a differentiated antithrombotic profile as both a monotherapy and in combination with antiplatelet therapy. These data also suggest a positive efficacy and bleeding profile in stroke patients where FXa inhibitors are not indicated.

About Milvexian*

Milvexian is an investigational, oral factor XIa (FXIa) inhibitor (antithrombotic) being studied for the prevention and treatment of major thrombotic conditions as

part of the Librexia program, the most comprehensive FXIa clinical development program to date.

*Milvexian is an investigational agent and has not been approved for use in any country, for any indication.

About the Librexia Program

The Librexia program is unrivaled as the most comprehensive FXIa clinical development program to date, studying nearly 50,000 patients across three parallel clinical trials (Librexia STROKE, Librexia ACS and Librexia AF). Grounded in positive Phase 2 efficacy and safety data, the Librexia program aims to investigate whether milvexian can enhance the benefit-risk profile associated with treating patients with these three conditions by delivering reduced thrombotic events with no increased risk of bleeding. The program is designed to potentially advance beyond the standard of care and help improve outcomes in a wide range of patients with thrombotic diseases. Each indication under evaluation in the Librexia program has received Fast Track Designation from the U.S. Food and Drug Administration (FDA). Librexia STROKE, Librexia ACS and Librexia AF are dosing patients.

About Librexia STROKE

Librexia STROKE is a Phase 3, randomized, double-blind, parallel-group, placebo-controlled study to demonstrate the efficacy and safety of milvexian in addition to single or dual antiplatelet therapy for stroke prevention after an acute ischemic stroke or high-risk transient ischemic attack (TIA). More information can be found on http://www.clinicaltrials.gov (NCT05702034).

About Librexia ACS

Librexia ACS is a randomized, double-blind, placebo-controlled, event-driven study to demonstrate the efficacy and safety of milvexian after a recent acute coronary syndrome. More information can be found on http://www.clinicaltrials.gov (NCT05754957).

About Librexia AF

Librexia AF is a randomized, double-blind, double-dummy, parallel group, active-controlled study to evaluate the efficacy and safety of milvexian versus apixaban in participants with atrial fibrillation. More information can be found on http://www.clinicaltrials.gov (NCT05757869).

About the Bristol Myers Squibb/Janssen Collaboration

Bristol Myers Squibb and the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), two unsurpassed leaders in cardiovascular care, are determined to close the gap in unmet needs in thrombosis management by overcoming the limits of today's treatments. The collaboration to develop and commercialize milvexian aims to leverage the combined scientific heritage and world-class commercial capabilities of each company, all in service of improved patient outcomes. The alliance is uniquely equipped to deliver on the promise of FXIa inhibitors and is working diligently to ensure cutting-edge safe and effective treatment options are available for patients.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private

Securities Litigation Reform Act of 1995 regarding milvexian. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[i] Dr. Harrington is affiliated with Stanford University and was provided payment for his participation in the Phase 3 Librexia program.