Xeris Pharmaceuticals Announces FDA Acceptance of its IND Application for XeriSol™ Levothyroxine (XP-8121) for the Treatment of Hypothyroidism

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Currently recruiting healthy participants

CHICAGO--(BUSINESS WIRE)--Aug. 11, 2021-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced that the Food and Drug Administration (FDA) has allowed the Investigational New Drug Application (IND) for its XeriSol levothyroxine for hypothyroidism to proceed. The active IND enables Xeris to initiate a Phase 1 clinical study for XP-8121 using its novel formulation of levothyroxine in a subcutaneous injection for the treatment of hypothyroidism. The Phase 1 study will characterize Pharmacokinetics (PK) and evaluate the safety and tolerability of XP-8121 in healthy participants.

“Levothyroxine is one of the most widely prescribed drug products in the United States. However, due to the many challenges associated with oral formulations there remains an area of significant unmet need. We believe that a potentially weekly subcutaneous injection of XeriSol levothyroxine can mitigate many of these challenges and improve compliance. The Phase 1 study is the first step toward addressing this unmet need,” said Kenneth E. Johnson, PharmD, Xeris’ Senior Vice President of Global Development and Medical Affairs.

“The FDA acceptance of our XP-8121 further underscores the applicability of our XeriSol technology and progress of our pipeline. We will continue to invest in our pipeline in therapeutic areas where we have an established commercial footprint,” said Paul R. Edick, Chairman and CEO of Xeris.

About Levothyroxine and Hypothyroidism

The thyroid gland is responsible for the synthesis, storage, and release of metabolic hormones including thyroxine (T4) and triiodothyronine (T3) [Colucci et al, 2013]. These hormones are crucial in the regulation of critical metabolic processes and are vital for normal growth and development during fetal life, infancy, and childhood.

Therapeutically, levothyroxine is administered when the body is deficient in the endogenous hormone. The goal of therapy is restoration of the euthyroid state which can reverse the clinical manifestations of hypothyroidism and significantly improve quality of life [Winther et al, 2016]. The treatment of choice for correction of hypothyroidism is levothyroxine, which is the mainstay of thyroid hormone replacement therapy. It is one of the most widely prescribed drug products in the United States, but the complexity of maintaining biochemical and clinical euthyroidism in patients undergoing treatment with oral levothyroxine cannot be underestimated. It has been reported that nearly 40% of patients undergoing treatment with oral levothyroxine are either over- or under-treated [Laurent et al, 2018] due to factors that include, but are not limited to, drug formulation, use of the drug with food, adherence to the drug, use of concomitant medications, and pre-existing medical conditions. Many patients failing to reach target TSH levels are generally managed by simply increasing their levothyroxine daily dose [Chiovato et al, 2019]. However, levothyroxine is a drug with a narrow therapeutic index [Vita et al, 2014], meaning that relatively small deviations from the proper dose can cause a clinically meaningful shift in pharmacological effects when administered to a patient; thus, the titration of levothyroxine oral drug may be a tailored and incremental process.

About Xeris Pharmaceuticals, Inc.

Xeris (Nasdaq: XERS) is a pharmaceutical company delivering innovative solutions to simplify the experience of administering important therapies that people rely on every day around the world.

With a novel technology platform that enables ready-to-use, room-temperature stable formulations of injectable, the company is advancing a portfolio of solutions in various therapeutic categories, including its first commercial product, Gvoke® in the U.S. Its proprietary XeriSol™ and XeriJect™ formulation technologies have the potential to offer distinct advantages over conventional product formulations, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. With Xeris’ technology, new product formulations are designed to be easier to use by patients, caregivers, and health practitioners and help reduce costs for payers and the healthcare system.

Xeris is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on Twitter, LinkedIn or Instagram.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements regarding the market and therapeutic potential of its products and product candidates, expectations regarding clinical data or results from planned clinical trials, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing and likelihood of the consummation of the Strongbridge Biopharma acquisition, the timing or likelihood of expansion into additional markets, the timing or likelihood of identifying potential development and commercialization partnerships, the potential utility of its formulation platforms and other statements containing the words "will," "would," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, without limitation, the impact of COVID-19 on its business operations, its reliance on third-party suppliers for Gvoke® and Ogluo®, the regulatory approval of its product candidates, its ability to market and sell its products, if approved, and other factors discussed in the "Risk Factors" section of the most recently filed Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission (the “SEC”), as well as discussions of potential risks, uncertainties, and other important factors in Xeris’ subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking

statements, whether as a result of new information, future events or otherwise.

The Company intends to use the investor relations portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

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