Xeris Biopharma Announces Plans for a Phase II Dose-Finding Study for Its Investigational Subcutaneous (SC) Levothyroxine (XP-8121) as Replacement Therapy for Hypothyroidism

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Targeting initiation of a Phase II study by 2H 2023

CHICAGO--(BUSINESS WIRE)--Dec. 15, 2022-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, today announced that, based on feedback from a Type C meeting with the Food and Drug Administration (FDA), Xeris will proceed with a Phase II study in patients for its novel formulation of levothyroxine sodium (SC injection) as replacement therapy for hypothyroidism. The Company anticipates initiating the study by the second half of 2023.

“We received very productive feedback from the FDA on our proposed clinical plan for our once weekly subcutaneous levothyroxine and are in the process of clarifying some aspects of the Phase II and Phase III recommendations. We believe we have enough clarity to move forward with a Phase II study, which we anticipate having up and running by the second half of 2023,” said Paul R. Edick, Xeris’ Chairman and CEO.

“We are excited to commence our Phase II dose-finding study of XP-8121 in 2023. The study will be designed to assess XP-8121 in patients receiving oral thyroid replacement therapy to establish the average once-weekly dose, accrue chronic safety data, and facilitate a future Phase III program in consultation with the FDA,” said Ken Johnson, PharmD, Xeris’ Senior Vice President, Global Development and Medical Affairs.

In October, Xeris reported positive topline Phase I data of XP-8121. The data show that subjects receiving XP-8121 SC have slower absorption, lower peak plasma, and higher extended exposure compared to Synthroid PO at the comparable dose of 600 µg. In addition, exposure was proportional over the range of ascending XP-8121 doses studied. Simulations based on the population pharmacokinetic model indicate that exposure from weekly XP-8121 1200 µg SC doses overlaps daily Synthroid PO 300 µg suggesting a dose conversion factor of 4x. Importantly, single SC doses of XP-8121 at all doses were safe and well tolerated and no XP-8121 studied dose was different from Synthroid 600 µg PO with respect to the safety findings.

About Hypothyroidism

Hypothyroidism, or underactive thyroid, happens when your thyroid gland doesn't make enough thyroid hormones to meet your body's needs. Your thyroid is a small, butterfly-shaped gland in the front of your neck. It makes hormones that control the way the body uses energy. These hormones affect nearly every organ in your body and control many of your body's most important functions. For example, they affect your breathing, heart rate, weight, digestion, and moods. Without enough thyroid hormones, many of your body's functions slow down.

About Levothyroxine

Therapeutically, levothyroxine is administered when the body is deficient in the endogenous hormone. Administration of levothyroxine is thus indicated for acquired thyroid disease (primary hypothyroidism), in cases of decreased secretion of TSH from the anterior pituitary gland (secondary hypothyroidism), and in cases of decreased secretion of TRH from the hypothalamus (tertiary hypothyroidism) and for congenital hypothyroidism. In most patients, hypothyroidism is a permanent condition requiring lifelong treatment. The goal of therapy is restoration of the euthyroid state, which can reverse the clinical manifestations of hypothyroidism and significantly improve quality of life.

About XeriSol™

The proprietary XeriSol™ non-aqueous formulation technology platform is designed to address the limitations of aqueous formulations for peptide and small molecule drugs. The solutions are formulated using biocompatible, non-aqueous solutions that impart high stability and solubility to drugs allowing for development of room temperature stable, ready-to-use formulations. XeriSol™ formulations have been used extensively in global commercial products (Gvoke®/Ogluo®) and clinical trials. The technology is protected by an extensive patent estate, trade secrets and know-how, and it is available for licensing.

About Xeris

Xeris (Nasdaq: XERS) is a growth-oriented biopharmaceutical company committed to improving patients’ lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, Keveyis®, the first and only FDA-approved therapy for primary periodic paralysis, and Recorlev® for the treatment of endogenous Cushing’s syndrome. Xeris also has a pipeline of development programs to extend the current marketed products into important new indications and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect™, supporting long-term product development and commercial success.

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

Forward-looking Statement

Any statements in this press release about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the development of a sub-cutaneous formulation of levothyroxine, the market and therapeutic potential of Xeris’ products and product candidates, expectations regarding clinical data or results from planned clinical trials, the timing of clinical trials, the timing or likelihood of regulatory feedback, regulatory approval, or commercialization of its product candidates, the timing, likelihood or nature of expansion of current marketed products into new indications and uses or

into additional markets, the potential utility of its proprietary formulation technology platforms, and other statements containing the words “expected,” “will,” “would,” “continue,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris’ experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Various factors could cause Xeris’ actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, including the impact of COVID-19 on our business operations and clinical activities, our ability to fund our product development programs or commercialization efforts, whether our clinical trials demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, and whether our products will achieve and maintain market acceptance. No assurance can be given that our expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional information about economic, competitive, governmental, technological, and other factors that may affect Xeris is set forth in the "Risk Factors" section of the most recently filed Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form a part of, this communication. Forward-looking statements in this communication are based upon information available to Xeris, as of the date of this communication and, while believed to be reasonable, actual results may differ materially. Subject to any obligations under applicable law, Xeris does not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

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