Xeris Biopharma Announces First Participant Dosed in a Phase 2 Clinical Study of Its Investigational Subcutaneous (SC) Levothyroxine (XP-8121) in Patients With Hypothyroidism

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Novel formulation of levothyroxine sodium (SC injection) to potentially mitigate many of the challenges associated with oral formulations of levothyroxine.

Phase 2 study to establish the average once-weekly dose, accrue additional safety data, and facilitate a future Phase 3 program

CHICAGO--(BUSINESS WIRE)--Jun. 21, 2023-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing innovative products across a range of therapies, today announced that the first participant has been dosed in a multi-center, open label, Phase 2 study of XP-8121 for the treatment of adults with hypothyroidism.

"Oral levothyroxine is one of the most prescribed medicines in the United States, generating more than 100 million prescriptions per year. However, many patients experience one or more challenges associated with the oral therapy. We believe that our novel SC formulation of levothyroxine has the potential to provide patients with a once-weekly dosing, thereby potentially improving treatment adherence, as well as bypass the gastrointestinal (GI) tract," said Paul R. Edick, Xeris' Chairman and CEO.

"We are excited to have dosed the first participant in our Phase 2 dose-finding study of XP-8121 and are actively recruiting additional participants that meet the eligibility criteria. We anticipate a lengthy recruitment period as enrolling stably dosed patients with normal TSH on oral levothyroxine is challenging and speaks further to the need of developing a once-weekly SC injection," said Kenneth E. Johnson, PharmD, Xeris' Senior Vice President, Global Development and Medical Affairs. "Depending upon enrollment rates, we anticipate completing the study in the first half of 2024."

The Phase 2 study (NCT05823012) is a non-randomized, open-label, single arm, self-controlled study of XP-8121 (levothyroxine sodium) to determine a target dose conversion factor from stably dosed oral levothyroxine to XP-8121 (levothyroxine sodium) in patients with hypothyroidism and to assess the safety and tolerability of XP-8121 (levothyroxine sodium) after once-weekly subcutaneous injections. This study includes the following periods: Screening, Titration Period (2 to 8 weeks), and Maintenance Period (4 weeks). A pharmacokinetic sub-study will be conducted for a subset of patients during the Maintenance Period.

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 Xeris

Xeris (Nasdaq: XERS) is a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing differentiated and 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®, a proven therapy for primary periodic paralysis; and Recorlev® for the treatment of endogenous Cushing's syndrome. Xeris has a diverse pipeline of development and partnered programs using its formulation sciences, XeriSol™ and XeriJect™, to support 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 Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the potential benefits of its novel SC formulation of levothyroxine, its ability to recruit additional clinical trial subjects, the anticipated completion date of the Phase 2 dose-finding study of XP-8121, the market and therapeutic potential of its products and product candidates, the potential utility of its formulation platforms, and other statements containing the words "will," "would," "continue," "expect," "anticipate" 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, geopolitical factors 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. The various factors that 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, include its financial position and need for financing, including to fund its

product development programs or commercialization efforts, whether its products will achieve and maintain market acceptance in a competitive business environment, its reliance on third-party suppliers, including single-source suppliers, its reliance on third parties to conduct clinical trials, the ability of its product candidates to compete successfully with existing and new drugs, and its and collaborators' ability to protect its intellectual property and proprietary technology. No assurance can be given that such 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 potential impacts of COVID-19, financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Xeris can be found in Xeris' filings, including its most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to us, 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, we do 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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