Xeris Pharmaceuticals Completes Enrollment of Its Phase 1 Study of Levothyroxine (XP-8121)

September 1, 2021

All participants received initial dose

Preliminary results anticipated in Q1 2022

Compelling pre-clinical data show potential for subcutaneous administration

CHICAGO--(BUSINESS WIRE)--Sep. 1, 2021-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable drug formulations, today announced that the company has completed enrollment and successfully dosed all participants in a Phase 1 study of levothyroxine (XP-8121) to evaluate the pharmacokinetics, safety and tolerability, and potential for weekly dosing of the investigational, novel, subcutaneous (SC) injection for the treatment of hypothyroidism.

XP-8121 is a novel formulation that could potentially mitigate many of the challenges associated with oral formulations, such as identification of an ideal dose due to absorption variation and medication adherence for patients who have difficulty maintaining a stable, therapeutic serum level. Preclinical studies of SC XP-8121 showed a sustained plasma exposure profile and similar maximum plasma concentration (Cmax) when compared with equivalent doses of the oral formulation.

The Phase 1 clinical study of levothyroxine (XP-8121) is a single ascending dose crossover design in 30 healthy participants to compare matching doses of oral levothyroxine (Synthroid®) and subcutaneous (SC) XP-8121. The primary endpoints of the study are to characterize the absorption and elimination kinetics of XP-8121 and compare bioavailability of XP-8121 to oral levothyroxine. Secondary endpoints are safety and tolerability of XP-8121. The study is being conducted in partnership with Dr. Danielle Armas and Celerion, a leading contract research organization with extensive experience performing first-in-human studies.

“The potential for a once weekly subcutaneous injection of levothyroxine would represent a promising novel approach in treating patients with hypothyroidism. Drug non-compliance, resistant hypothyroidism, and limited GI absorption are some of the major reasons for treatment failure or suboptimal treatment with oral levothyroxine. These challenges could be mitigated by XP-8121 and translate into the long-term health benefit of achieving a euthyroid state for patients,” said Dr. Armas, Senior Principal Investigator, Celerion.

“Because our levothyroxine formulation enables a small volume SC injection, as an injectable maintenance therapy, it may facilitate less frequent dosing. This may provide clinical advantages over the established oral daily route, by providing predictable bioavailability, comparable safety, and ease of use,” said Dr. Ken Johnson, Xeris’ Senior Vice President of Global Development and Medical Affairs.

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 drug, 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.

About Celerion

A recognized global leader in early clinical research services, Celerion "translates science into medicine" through scientific excellence, medical expertise, and broad clinical operations experience.

For fifty years Celerion has been providing industry leadership in the execution of safety/tolerability, pharmacokinetic and pharmacodynamics studies in highly controlled clinical environments such as first-in-human dose escalation, drug-drug interaction, cardiac safety, bioequivalence and bioavailability, metabolism and excretion, as well as pharmacokinetic evaluations in patients with impaired renal or hepatic function.

Celerion enhances this with superior data management, biostatistics, clinical monitoring, and bioanalytical services. Our enduring mission is to help clients get their drugs to market in a timely fashion that benefits people in need the world over. For more information, please visit www.celerion.com.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210901005212/en/

Investor Contact
Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com
312-736-1237

Source: Xeris Pharmaceuticals, Inc.