Xeris Pharmaceuticals Announces Positive Results from the In-Clinic Stage of a Phase 2 Study of Its Developmental Ready-To-Use (RTU) Glucagon in Patients at Risk of Hypoglycemia During and after Aerobic Exercise

January 6, 2020

Results show a mini dose (150 µg) of RTU glucagon prevents Exercise-Induced Hypoglycemia (EIH) during prolonged, moderate-to-high intensity aerobic exercise in a clinical research setting

CHICAGO--(BUSINESS WIRE)--Jan. 6, 2020-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced positive topline results from the in-clinic stage of a Phase 2 study of its developmental ready-to-use (RTU) glucagon for the prevention of hypoglycemia during and after moderate-to-high intensity aerobic exercise in adults with Type 1 diabetes mellitus (T1D).

Results from the in-clinic stage of the Phase 2 Exercise-Induced Hypoglycemia (EIH) study show that a mini dose of RTU glucagon was adequate to maintain normal blood glucose levels during prolonged, moderate-to-intense aerobic exercise. Episodes of hypoglycemia were observed both during and after the prescribed exercise session. Overall, there were more EIH episodes among subjects who received standard of care (placebo plus 50% insulin pump reduction) than subjects who received RTU glucagon plus 50% insulin pump reduction. The use of glucose tablets to treat hypoglycemia during and after exercise was less with RTU glucagon when compared to standard of care. Treatment-emergent adverse events with a mini dose of RTU glucagon were comparable to placebo, including negligible injection site reactions. In this phase of the study, mini doses of RTU glucagon were safe and well tolerated, and no serious adverse events occurred.

“For people with Type 1 diabetes, prolonged and vigorous aerobic exercise can be dangerous if not planned out and executed carefully. The current standard of care includes multiple preparation steps, such as insulin pump reduction well before exercise, and eating high glucose foods before, during, and after the exercise session. These steps can be a barrier to exercise, and therefore, many people with diabetes do not achieve 2 ½ hours of aerobic exercise per week as per ADA guidelines,” said Paul R. Edick, Xeris’ Chairman and CEO. “Our goal with this study is to show that a mini dose (150 µg) of Xeris’ liquid stable glucagon, administered immediately prior to aggressive aerobic exercise, can alleviate this burden and prevent exercise-induced hypoglycemia. This data from the in-clinic portion of our ongoing Phase 2 study, we believe indicates that we can do just that. The second half of the study, where subjects will be exercising on their own at home, will inform us further as to the safety and effectiveness of using mini doses of glucagon to reduce the risk of experiencing hypoglycemia during exercise for this population.”

This study is a randomized, placebo-controlled, double-blind, two-treatment, two-period, crossover comparison in a clinical research center setting, followed by a randomized, placebo-controlled, two-treatment double-blind with a parallel open label, 3-arm comparison in an outpatient setting to evaluate the preliminary efficacy and safety of RTU glucagon to prevent EIH in adults with T1D, who perform regular, moderate-to-high intensity aerobic exercise. The in-clinic stage is now unblinded and complete, while the blinded outpatient stage is currently ongoing. The results of the outpatient stage will be available in the first half of 2020. For more information, visit www.clinicaltrials.gov Identifier: NCT03841526.

About Exercise-Induced Hypoglycemia (EIH)

For persons with diabetes, especially with T1D, the lack of pancreatic β-cell function leads to the requirement for exogenous insulin (introduced into the body by injection or infusion). Circulating levels of insulin consequently cannot be regulated endogenously and depend on the quantity and timing of insulin taken by the individual before exercise. Thus, insulin levels are often higher than they would be in the absence of diabetes, which has the result of limiting glucose production by the liver while stimulating glucose uptake by muscle, adipose, and liver cells for storage. As a result, blood glucose levels often decrease dramatically during physical activity for individuals with T1D unless carbohydrates are consumed before, during, and after exercise. This condition of low blood glucose with physical activity is known as EIH.

About Glucagon

Glucagon is a metabolic hormone secreted by the pancreas that raises blood glucose levels by causing the liver to rapidly convert glycogen (the stored form of glucose) into glucose, which is then released into the bloodstream. Glucagon and insulin are two critical hormones in a glycemic control system that keep blood glucose at the right level in healthy individuals. In people with diabetes who are dependent on insulin, this control system is disrupted, and insulin must be injected to avoid high levels of blood glucose (hyperglycemia). The opposite effect, or low blood glucose (hypoglycemia), is also prevalent in this population due to dysregulated glucagon secretion. Severe hypoglycemia is a serious condition and can lead to seizures, coma, potential brain injury and, if untreated, death.

Glucagon is the standard of care for treating severe hypoglycemia. According to the American Diabetes Association, glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L). Leveraging XeriSol™, one of Xeris’ two proprietary formulation technology platforms, Xeris has the potential to provide the first ready-to-use, room-temperature stable liquid glucagon for use by people with diabetes and other conditions to prevent or manage various forms of hypoglycemia and improve glucose control.

About Xeris Pharmaceuticals, Inc.

Xeris (Nasdaq: XERS) is a specialty 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 and infusible therapies, the company is advancing a portfolio of solutions in various therapeutic categories, including its first commercial product, Gvoke™. Its proprietary XeriSol™ and XeriJect™ formulation technologies have the potential to offer distinct advantages ove

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 acceptance of Gvoke™ in the marketplace, the market and therapeutic potential of its product candidates, expectations regarding clinical data, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, expectations regarding the timing of the commercial launch of Gvoke HypoPen™, 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 regulatory approval of its product candidates, its ability to market and sell its products, if approved, its reliance on a single source supplier for Gvoke HypoPen™ and other factors discussed in the "Risk Factors" section of the most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Xeris' subsequent filings with the Securities and Exchange Commission. 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/20200106005951/en/

Source: Xeris Pharmaceuticals, Inc.

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