Xeris Pharmaceuticals Announces Positive Topline Results From the In-clinic Stage of the Phase 2 Study of Its Developmental Ready-to-use (RTU) Glucagon in Patients at Risk of Postprandial Hypoglycemia Following Bariatric Surgery

December 10, 2019

All subjects successfully self-administered a mini dose of RTU glucagon

Rebound hypoglycemia observed more frequently in the placebo arm and with oral glucose tablet use

Subcutaneous RTU glucagon is safe and well-tolerated

CHICAGO--(BUSINESS WIRE)--Dec. 10, 2019-- 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 in patients who experience postprandial hypoglycemic episodes following bariatric surgery.

This is a Phase 2 prospective, randomized, placebo-controlled, double-blind study that comprises an in-clinic stage followed by a 12-week outpatient stage. Subjects are randomly assigned to receive RTU glucagon or placebo during two separate meal challenges in an in-clinic stage crossover design, and then enter a parallel design outpatient stage where they are assigned to an investigational product for 12 weeks. In this study, subjects self-administer a mini dose (300 µg) of RTU glucagon or placebo when they experience hypoglycemia symptoms (e.g., anxiety, nausea, sweating, tremors, palpitations), and blood glucose response is measured after the study drug is self-administered. In situations where hypoglycemia (blood glucose ≤ 70 mg/dl) is present at mini-dosing or continues after treatment, oral glucose tabs are used in addition to the study drug. The in-clinic stage is now complete, and this study is currently ongoing in the outpatient stage, where both subjects and investigators remain blinded. For more information, visit www.clinicaltrials.gov Identifier: NCT03770637

Results from the in-clinic stage of this Phase 2 study demonstrate that most subjects experienced postprandial hypoglycemia within 90-120 minutes after finishing the meal. Of patients with a successful meal challenge, all subjects were also able to self-administer a mini dose of study drug, as directed, during the setting of declining blood glucose. A mini dose of RTU glucagon was adequate to restore or maintain normal blood glucose levels within 15 minutes of administration. This effect was maintained at 30 minutes, and hyperglycemia was not observed. The incidence of a follow-on episode of hypoglycemia (rebound hypoglycemia) requiring oral glucose for rescue was less with RTU glucagon compared to placebo. Treatment emergent adverse events with a mini dose of RTU glucagon were comparable to placebo, including negligible injection site reactions. Mini doses of RTU glucagon appear safe and well tolerated, and no serious adverse events occurred.

“We are encouraged by the results of the in-clinic stage of our PBH study. The first half of this study is an important first step in demonstrating the utility of liquid, stable, ready-to-use glucagon in conditions beyond rescue for severe hypoglycemia and demonstrating safety and effectiveness in situations that require self-administration by the patient,” said Paul R. Edick, Xeris’ Chairman and CEO. “We believe the second half of the study, which is outside of the controlled in-clinic environment, will go further in establishing the safety profile of mini dosing RTU glucagon. That additional data will be available in the first half of 2020.”

About Post-Bariatric Hypoglycemia (PBH)

Approximately 200,000 weight loss (bariatric) surgeries are performed annually in the United States. Hypoglycemia that occurs after bariatric and other forms of upper gastrointestinal surgery is a condition called post-bariatric hypoglycemia (PBH). It usually occurs >6 months to 8 years after surgery and is an uncommon and rarely reported metabolic complication that can be severe and disabling for some patients. Hypoglycemia episodes from PBH occur 1-3 hours after meals (postprandial hypoglycemia), often at a frequency of >10 times per month. Persistent or unrecognized hypoglycemia from PBH can progress to severe hypoglycemia (blood glucose <54 mg/dL) with symptoms such as loss of consciousness, seizures, coma, and even death. When postprandial hypoglycemia episodes in PBH occur, they can be difficult to acutely treat with oral carbohydrates alone, because an overcompensation with oral carbohydrates can frequently trigger a subsequent hypoglycemia episode (rebound hypoglycemia).

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.

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