Xeris Pharmaceuticals Doses First Patient in Phase 2 Trial Evaluating Its Developmental Ready-to-use Glucagon in Patients at Risk From Hypoglycemia Following Bariatric Surgery

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CHICAGO--(BUSINESS WIRE)--Jun. 27, 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 that is has dosed the first subject in a Phase 2 trial with its developmental ready-to-use glucagon in patients who experience hypoglycemic episodes following bariatric surgery.

Post-bariatric hypoglycemia (PBH) is a complication of bariatric surgery thought to be related to excessive insulin secretion in response to a meal. PBH can begin to occur one to eight years after gastric bypass surgery. These severe hypoglycemic episodes are characterized by extremely low blood sugar levels that occur two to three hours after a meal.

“The risk of hypoglycemic events can persist well beyond the initial recovery from post-bariatric surgery. Our goal is to determine if our ready-to-use glucagon can provide the reassurance of an effective treatment to promptly address these events if and when they occur, to support the patient’s continued recovery,” said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. “Just weeks after initiating a similar study in exercised-induced hypoglycemia, we’re continuing to fuel a diverse and growing pipeline to evaluate the potential for our ready-to-use glucagon to benefit patients who may experience hypoglycemic episodes in a range of settings.”

This Phase 2, randomized, placebo-controlled, double-blind study will evaluate the efficacy, safety and tolerability of the Xeris ready-to-use glucagon in treating symptomatic postprandial hypoglycemia among 12 patients with PBH initially during two in-patient clinical research center visits, and then ongoing as part of a 12-week outpatient phase. Efficacy will be measured during confirmed hypoglycemic episodes by plasma glucose recovery (blood glucose >70 mg/dL) at 15 minutes after dosing with ready-to-use glucagon or placebo.

Xeris expects top-line data from the in-patient portion of the study in the second half of 2019. For more information, visit clinicaltrials.gov, identifier NCT03770637.

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 indications to prevent or manage various forms of hypoglycemia and improve glucose control.

About Severe Hypoglycemia

Hypoglycemic events of any severity are a daily concern for people with diabetes. Mild or moderate hypoglycemia can occur multiple times a month. Severe hypoglycemia is characterized by severe cognitive impairment, requiring external assistance for recovery, and can be extremely frightening for patients and caregivers. Severe hypoglycemia can result in cardiovascular disease, seizure, coma, and, if left untreated, death. These severe hypoglycemic events can occur multiple times a year. Such events require emergency assistance from another person or caregiver such as a family member, friend, or co-worker.

About Xeris Pharmaceuticals, Inc.

Xeris is a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use, room-temperature stable injectable and infusible drug formulations. The Company’s proprietary XeriSol™ and XeriJect™ formulation technologies are being evaluated for the subcutaneous (SC) and intramuscular (IM) delivery of highly-concentrated, non-aqueous, ready-to-use formulations of peptides, small molecules, proteins, and antibodies using commercially available syringes, auto-injectors, multi-dose pens, and infusion pumps. XeriSol™ and XeriJect™ have the potential to offer distinct advantages over existing formulations of marketed and development-stage products, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. These attributes may lead to products that are easier to use by patients, caregivers, and health practitioners and reduce costs for payers and the healthcare system. Further information about Xeris can be found at www.xerispharma.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements concerning the timing or likelihood of approval by the FDA of its NDA for its glucagon pen, the market and therapeutic potential of its product candidates, the timing or likelihood of commercialization of our product candidates, 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, 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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