Xeris Pharmaceuticals Achieves Phase 3 Milestones of its Ready-to-Use Glucagon Rescue Pen for the Treatment of Severe Hypoglycemia

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Chicago, IL, Feb. 15, 2018 (GLOBE NEWSWIRE) -- Xeris Pharmaceuticals, Inc. (“Xeris”), a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, announced the successful completion of two Phase 3 studies and a Human Factors usability and reliability study, and the initiation of a Phase 3b study of its investigational ready-to-use, liquid-stable glucagon rescue pen for treatment of severe hypoglycemia in people with diabetes.

Xeris has successfully completed two Phase 3 clinical studies of its investigational ready-to-use glucagon rescue pen (adult study: NCT02656069; pediatric study: NCT03091673). The company shared the data with the FDA in a pre-NDA meeting and plans to present the complete results at a medical conference later this year. Xeris also announced the initiation of a Phase 3b study of its rescue pen, the results of which are expected to complement the data collected in the already-completed Phase 3 clinical studies. “Xeris is on-track to submit an NDA for our ready-to-use glucagon rescue pen for the treatment of severe hypoglycemia in late Q2 of this year. We will use the data from the Phase 3b study to gain additional information regarding the entire treatment episode, including preparation and administration time of the current glucagon emergency kits versus our rescue pen auto-injector, for people with diabetes who may require glucagon in emergency situations,” said Paul Edick, President and CEO of Xeris.

Xeris has also announced results from a Human Factors usability and reliability study which showed 99% of participants were able to successfully administer a full dose of glucagon with Xeris’ rescue pen. The ready-to-use, liquid-stable glucagon formulation and auto-injector functionality of Xeris’ rescue pen allow for a simple 2-step administration process. The usability and reliability of an easy-to-administer device may give individuals more confidence in successfully administering the product in emergency situations. The full results of the Human Factors study will be presented February 14-17th in Vienna, Austria at the Advanced Technologies and Treatments for Diabetes (ATTD) conference.

People with diabetes on insulin are at risk of experiencing severe hypoglycemic events, characterized by altered mental and/or physical status requiring external assistance to treat, which can cause irreversible heart problems and brain damage. If emergency medical treatment is not provided in a timely manner, severe hypoglycemia can even be fatal. Glucagon treatment is the standard-of-care, and guidelines state that glucagon should be prescribed for all individuals at increased risk of experiencing a severe hypoglycemic event. However, today many people who are at risk of experiencing a severe hypoglycemic event do not carry glucagon. This is, in part, due to the limitations of current glucagon options all of which are powder, not ready-to-use and require a lengthy, complex, time-consuming, multi-step reconstitution and dose-calibration process, which studies have shown even trained personnel are prone to administer incorrectly.

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 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, proteins, antibodies, and small molecules using commercially available syringes, auto-injectors, multi-dose pens, and infusion pumps. Xeris' platforms have the potential to offer distinct advantages over existing formulations of marketed and development-stage products. In particular, XeriSol™ and XeriJect™ have the potential to eliminate the need for reconstitution, enable long-term room-temperature stability, significantly reduce injection volume, and eliminate 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.

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