DA Grants Orphan Drug Designation (ODD) for Xeris Pharmaceuticals' Ready-to-Use Glucagon for the Treatment of Hyperinsulinemic Hypoglycemia (HH).

February 8, 2018

Results from Phase 2a Study in Post-Bariatric Hypoglycemia, Associated with HH, Published.

Chicago, IL, Feb. 08, 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 today the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Xeris’ ready-to-use, liquid-stable glucagon for the treatment of Hyperinsulinemic Hypoglycemia. Xeris also announced the publication of a Phase 2a study of a mini-dose of its ready-to-use glucagon in Post-Bariatric Hypoglycemia (PBH).

Hyperinsulinemic Hypoglycemia (HH) describes a condition in which a person’s blood glucose levels become low, or hypoglycemic, due to excessive insulin secretion. ODD approval was given, in part, on the basis that mini-doses of Xeris’ ready-to-use glucagon may be more safe than similar drugs already approved.

HH is associated with several diseases, including Post-Bariatric Hypoglycemia (PBH). Today, there is no approved therapy for the treatment of PBH. Patients must rely on interventions including dietary changes, off-label acarbose to slow carbohydrate absorption and reduce insulin secretion, and/or a cocktail of additional off-label therapeutic options for hypoglycemia prevention. “Hypoglycemia can be a devastating complication of bariatric surgery. There is an urgent need for improved methods to treat severe hypoglycemia in this condition in order to maintain health, allow optimal nutrition, and improve safety. Having a ready-to-use, liquid, stable glucagon option may provide health care professionals and patients alike more options to treat and prevent severe hypoglycemia.” said Mary-Elizabeth Patti, M.D., F.A.C.P. of the Joslin Diabetes Center and Associate Professor of Medicine, Harvard Medical School.

The results of a Phase 2a study (NCT02733588) to validate the ability to successfully treat people with PBH with mini-doses of Xeris’ ready-to-use glucagon, was published last week in the journal Diabetes Technology & Therapeutics. Xeris and collaborators at Joslin Diabetes Center, an affiliate of Harvard Medical School, and Harvard John A. Paulson School of Engineering and Applied Sciences, with funding from NIH Fast-Track SBIR grant R44DK107114, studied mini-doses of Xeris’ glucagon delivered via subcutaneous infusion pump, guided by alerts from a continuous glucose monitor (CGM)-triggered low glucose prediction algorithm. The study confirmed that mini-doses of Xeris’ ready-to-use glucagon at specific blood glucose thresholds prevented severe hypoglycemia, with no rebound hyperglycemia. Primary Investigators in the clinical study included Mary-Elizabeth Patti, MD, from Joslin, and Eyal Dassau, PhD, from the Harvard John A. Paulson School of Engineering and Applied Sciences.

The Xeris, Joslin, and Harvard teams have also initiated a second Phase 2a study to test the optimized algorithm with mini-doses of Xeris’ ready-to-use, liquid-stable glucagon in a randomized, placebo-controlled, double-masked trial (NCT03255629). The study will assess the efficacy of the closed-loop system to prevent and treat hypoglycemia occurring in patients with PBH in response to a mixed-meal tolerance test or exercise. “This combination of emerging technology and stable liquid glucagon can provide a new way to prevent severe hypoglycemia as we demonstrate in this study and may pave the way to be the ‘airbag’ for people with diabetes.” said Dr. Dassau.

Of note, this is the third ODD Xeris has received. FDA previously granted Xeris ODDs for both its ready-to-use, pumpable liquid-stable glucagon for prevention of chronic, severe hypoglycemia related to Congenital Hyperinsulinism (CHI), as well as for a ready-to-use, liquid-stable formulation of diazepam for the treatment of Acute Repetitive Seizures (ARS) in patients with epilepsy.

About Post-Bariatric Hypoglycemia

Obesity and related comorbidities such as type 2 diabetes and cardiovascular disease are increasingly recognized as a major threat to individual and public health. Bariatric surgery has been shown to sustain weight loss, reduce mortality and improve measures of diabetes control. However, Roux-en-Y gastric bypass and sleeve gastrectomy can be associated with Post-Bariatric Hypoglycemia (PBH). PBH is defined as documented plasma glucose levels below 70 mg/dl in conjunction with neuroglycopenia, and the relief of these symptoms with the normalization of glucose levels. PBH typically occurs 1-3 years following bypass, and can lead to loss of consciousness, seizures, and motor vehicle accidents, particularly when patients are no longer aware of hypoglycemia onset – known as hypoglycemia unawareness.

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 keeps blood glucose at the right level in healthy individuals. 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 less than or equal to 54 mg/dL (3.0 mmol/L). XeriSol™, one of Xeris’ two proprietary formulation technology platforms, 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 achieve optimal 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 allow 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™ offer the opportunity to eliminate reconstitution, enable long-term room-temperature stability, significantly reduce injection volume, and eliminate the requirement for intravenous (IV) infusion. These attributes can 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.

Xeris Media Contact

www.xerispharma.com