FOR IMMEDIATE RELEASE

FDA and EMA Grant Orphan Designation to Xeris Pharmaceuticals' Soluble Glucagon for Prevention of Hypoglycemia in Congenital Hyperinsulinism Patients

AUSTIN, Texas, November 12, 2014 (GLOBE NEWSWIRE) – Xeris Pharmaceuticals, Inc. ("Xeris"), a clinical stage, specialty biopharmaceutical company developing novel, non-aqueous formulations of injectable drugs, announced today that the Food and Drug Administration has granted orphan drug designation for its soluble glucagon, an investigational new drug, for the prevention of severe, persistent hypoglycemia in patients with congenital hyperinsulinism (HI). Additionally, upon a recommendation by the European Medicines Agency's Committee for Orphan Medicinal Products (EMA COMP), the European Commission (EC) has also granted Xeris' soluble glucagon orphan designation for HI.

Both FDA and EMA grant orphan designation to promote the development of therapies to treat rare diseases. Incentives offered by FDA to companies to develop rare disease therapies include more frequent interaction with the FDA, tax credits related to development costs, waiver of prescription drug user fees for NDA submission, and a 7-year marketing exclusivity period in the U.S. following regulatory approval, and the potential for grant funding for clinical trial costs.

"We are pleased that both the FDA and EMA have recognized the importance of HI and designated orphan status for our soluble glucagon product for this indication." said Douglas R. Baum, Xeris' CEO. "Covered by multiple US Investigational New Drug applications, we are developing several soluble glucagon products for patients with diabetes, we believe our glucagon can be useful in a number of other patient populations, such as the HI population, who suffer from severe, persistent hypoglycemia".

Julie Raskin, the Executive Director of Congenital Hyperinsulinism International (CHI), the patient advocacy group for HI, offered that "CHI is very optimistic about the potential for Xeris' glucagon, particularly in the medical management of the diffuse form of HI which affects all the cells in the pancreas." Historically, many patients with diffuse HI have had to undergo surgery to remove 95-98% of their pancreas to reduce insulin secretion to a level that does not result in repeated hypoglycemic episodes. Raskin notes that "sadly, by 15 years of age, some 95% of these patients have insufficient insulin production and they become insulin-dependent for the remainder of their lives. We are very supportive of new drug products that have the potential to reduce the enormous emotional and financial burden of HI on patients and their families. Xeris soluble glucagon delivered via a pump is one of just a handful of new therapies to come along in 30 years."

About Congenital Hyperinsulinism

Congenital hyperinsulinism (HI) is the most frequent cause of severe, persistent hypoglycemia (very low blood sugar) in newborn babies and children. In most countries it occurs in approximately 1/25,000 to 1/50,000 births. About 60% of babies with HI develop hypoglycemia during the first month of life. An

additional 30% will be diagnosed later in the first year and the remainder after that. Congenital hyperinsulinism is a condition that causes individuals to have abnormally high levels of insulin, which is a hormone that helps control blood sugar levels. Infants and children with HI have frequent and severe episodes of hypoglycemia. In infants and young children, these episodes are characterized by a lack of energy, irritability, or difficulty feeding. Repeated episodes of low blood sugar increase in HI patients result in permanent seizure disorder, learning disabilities, cerebral palsy, blindness or even death.

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. In patients with HI, genetic defects cause the pancreas to continuously overexpress insulin. More commonly, glucagon is associated with people with diabetes who are dependent on insulin, where this control system is disrupted and insulin must be injected prior to meals to avoid high levels of blood glucose (hyperglycemia). The opposite effect of low blood glucose (hypoglycemia) is also prevalent in this population, resulting from too much insulin or exercise. Severe If untreated, this leads to severe hypoglycemia, which is a serious condition and can cause seizures, coma, potential brain injury and, death. Xeris proprietary glucagon formulation has the potential to provide the first soluble, room temperature stable, pump-delivered glucagon product for continuous infusion to combat high insulin levels and thus prevent severe hypoglycemia.

About Xeris Pharmaceuticals, Inc.

Xeris is an Austin, Texas-based, specialty biopharmaceutical company developing improved and differentiated injectable therapeutics for multiple indications including diabetes. The company's proprietary non-aqueous formulation technologies allow for the subcutaneous and intradermal delivery of highly concentrated, non-aqueous, ready-to-inject suspension and solution formulations of peptides, proteins, antibodies and small molecules. Xeris' proprietary formulation approach intends to offer distinct advantages over existing products and formulations including: up to 1000-fold lower injection volumes, eliminating the need for reconstitution and refrigeration, with extended room temperature shelf-life stability, all of which can lead to products that are easier to use by patients, caregivers, health practitioners, and that can reduce costs for payers and the healthcare system. For more information, please visit the Xeris website at: www.xerispharma.com

About Congenital Hyperinsulinism International

CHI is a leading nonprofit organization dedicated to improving the lives of children and adults living with congenital hyperinsulinism (HI). CHI provides a world of information, resources, and support to the HI community. CHI advocates on behalf of patients for better treatments and access to care. CHI is dedicated to increasing awareness of the disorder, as it leads to more timely diagnosis and the best outcomes for patients. CHI supports medical research for improved therapies, potential cures, and timely diagnosis. CHI works globally because cooperation across borders fosters important advances in medicine. For more information, please visit the CHI website at: www.congenitalhi.org

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