

#### FOR IMMEDIATE RELEASE

# Xeris Pharmaceuticals, Inc. Announces Dosing of First Patient in Phase 2 Clinical Trial of its Investigational Soluble Glucagon Formulation for Pumps

AUSTIN, Texas, April 24, 2014 (GLOBE NEWSWIRE) – Xeris Pharmaceuticals, Inc. ("Xeris"), a clinical stage, specialty biopharmaceutical company developing novel, non-aqueous formulations of injectable drugs, announced today the dosing of the first subject in a Phase 2 clinical study of the company's stable liquid glucagon in an Insulet Corporation OmniPod® infusion pump in patients with type 1 diabetes under a new US Investigational New Drug (IND) application. Xeris' G-Pump<sup>TM</sup> (glucagon infusion), a room-temperature stable glucagon solution, is a potentially effective and convenient treatment for hypoglycemia or low blood sugar. Currently, no commercial glucagon product is approved for use in any infusion pump. Glucagon is only approved and available in emergency kits (GEKs) marketed by Eli Lilly and Company and Novo Nordisk for the treatment of severe hypoglycemia. However, with these products, glucagon is available only as a dry powder in a sealed vial that must be reconstituted using a water-filled syringe in a multi-step process prior to injection. Xeris' glucagon formulation is a stable, ready-to-inject liquid which can be packaged and delivered with a variety of devices including auto-injectors, multi-dose pens and pumps.

"We are very pleased to announce the initiation of this Phase 2 clinical study under the direction of Principal Investigator, Jessica Castle, MD at the Oregon Health & Science University (OHSU) in Portland, Oregon," said Douglas R. Baum, Xeris' CEO. "Our G-Pump<sup>TM</sup> (glucagon infusion) is the 2<sup>nd</sup> Xeris glucagon product to enter Phase 2 testing. Our first glucagon product, G-Pen<sup>TM</sup> (glucagon injection) for severe hypoglycemia has successfully completed a Phase 2 trial recently. We are excited to investigate the use of our glucagon in new applications in addition to rescue use for severe hypoglycemia."

"Our team at Oregon Health & Science University is very excited to be collaborating with Xeris on a liquid glucagon suitable for use in pumps," said Dr. Jessica Castle. "The ability to administer glucagon from an infusion pump for a sustained period of time will be a major advance in the development of a bihormonal artificial pancreas system to maintain normal glucose levels in an automated manner for patients with diabetes," she added.

This Phase 2 clinical study is a single center, double-blind, randomized, two treatment, crossover trial in adult patients with type 1 diabetes. The study is designed to evaluate the safety, tolerability, and comparative pharmacokinetics and pharmacodynamics of Xeris' G-Pump<sup>TM</sup> (glucagon infusion) formulation relative to freshly reconstituted GlucaGen® (glucagon [rDNA origin] for injection) when delivered via an OmniPod® pump. The primary endpoint of the study is to assess the speed of glucagon absorption and onset of action of G-Pump<sup>TM</sup> (glucagon infusion) in raising blood glucose at three doses as compared to GlucaGen®. Xeris plans to use G-Pump<sup>TM</sup> (glucagon infusion) in a follow-on bi-hormonal

artificial pancreas clinical study in adult patients with type 1 diabetes. This study expects to involve wireless, automated insulin and G-Pump<sup>TM</sup> (glucagon infusion) delivery as determined by sensed glucose values input into a computer algorithm.

Xeris wishes to acknowledge the financial support for the clinical trial from a Small Business Innovation Research (SBIR) grant 4R44DK096706-02 from the National Institute of Diabetes Digestive and Kidney Diseases, and a partnership with JDRF, the leading global organization funding type 1 diabetes research. "Acute and chronic hypoglycemia are serious risk factors in several individuals affected by type 1 diabetes", said Sanjoy Dutta, Ph.D., senior director of translational development at JDRF, and added, "The development of automated multi-hormonal artificial pancreas systems leveraging the function of pumpable glucagon to reset the missing hormonal balance is thus a key priority of JDRF".

## **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 people with diabetes who are dependent on insulin, 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 followed by too small a meal without enough carbohydrates. Severe hypoglycemia is a serious condition and can lead to seizures, coma, potential brain injury and, if untreated, death. Xeris proprietary formulation has the potential to provide the first soluble, stable, ready to inject glucagon for use by people with diabetes to manage both moderate and severe hypoglycemia.

# About Xeris Pharmaceuticals, Inc.

Xeris is an Austin, Texas-based, specialty biopharmaceutical company developing improved and differentiated injectable drugs for indications including diabetes. The company's proprietary non-aqueous formulation technologies allow for the subcutaneous and intradermal delivery of highly concentrated, non-aqueous paste and liquid 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 reconstitution and refrigeration, with extended room temperature shelf-life stability, all of which can lead to products that can be self-administered, easier to use and reduce health care costs for millions of patients and caregivers. For more information please visit the Xeris website at: www.xerispharma.com

## **About Insulet Corporation**

Insulet Corporation (NASDAQ: PODD) is an innovative medical device company dedicated to making the lives of people with diabetes easier. Through its OmniPod Insulin Management System, Insulet seeks to expand the use of insulin pump therapy among people with insulin-dependent diabetes. The OmniPod is a revolutionary and easy-to-use tubeless insulin pump that features just two parts and fully-automated cannula insertion. Insulet's subsidiary, Neighborhood Diabetes, is a leading distributor for diabetes products and supplies, delivered through a high touch customer service model. To read inspiring stories of people with diabetes living their lives to the fullest with OmniPod, visit our customer blog, Suite D:

http://suited.myomnipod.com. Founded in 2000, Insulet Corporation is based in Bedford, Mass. For more information, please visit: <a href="http://www.myomnipod.com">http://www.myomnipod.com</a>.

#### **About JDRF**

JDRF is the leading global organization funding type 1 diabetes (T1D) research. JDRF's goal is to progressively remove the impact of T1D from people's lives until we achieve a world without T1D. JDRF collaborates with a wide spectrum of partners and is the only organization with the scientific resources, regulatory influence, and a working plan to better treat, prevent, and eventually cure T1D. As the largest charitable supporter of T1D research, JDRF is currently sponsoring \$568 million in scientific research in 17 countries. For more information, please visit www.jdrf.org.

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