



## Xeris Pharmaceuticals Releases Additional Phase 3 Clinical Trial Data on Its Ready-to-Use Liquid Glucagon Pen

November 12, 2018

*Positive efficacy and utility data presented during the 18th Annual Diabetes Technology Meeting*

CHICAGO, IL; November 12, 2018 – 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 the presentation of additional data supporting the efficacy and functional utility of its investigational ready-to-use, room-temperature stable liquid glucagon pen during the 18<sup>th</sup> Annual Diabetes Technology Meeting in North Bethesda, MD, November 8-10, 2018. The additional data supported the company's recent filing to the U.S. Food and Drug Administration (FDA) for regulatory approval.

The data from three posters provide a closer look at the ease of use and effectiveness of the Xeris investigational glucagon pen as an alternative to currently marketed rescue systems, which require complex, multi-step preparation and administration processes. These data outline the glucagon pen's efficacy in prompt and complete resolution of hypoglycemia in both adults and children with diabetes, as well as simplicity to facilitate successful administration during these critical settings.

"Hypoglycemia can quickly evolve from a mild event to an emergency, so prompt and reliable intervention is critically important. Robust research supports our investigational ready-to-use liquid glucagon pen as an effective, user-friendly alternative to currently marketed products," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "On the heels of our recent regulatory filing, we are now actively working toward our goal of introducing this important innovation to the diabetes community."

### **A Phase 3 Comparison of a Ready-to-use Liquid Glucagon Pen to Glucagon Emergency Kit for the Symptomatic Relief of Severe Hypoglycemia ([Poster CHRI1830D](#))**

The Phase 3, randomized, controlled, single-blind, crossover clinical trial compared the Xeris glucagon pen to the currently available Glucagon Emergency Kit (GEK) to treat severe hypoglycemia in 81 adults with type 1 diabetes. The study demonstrated that the Xeris glucagon pen is practical and efficient in resolving symptoms of hypoglycemia. Key findings include:

- All participants achieved successful plasma glucose recovery. The average time to symptom relief was comparable for autonomic symptoms (9.9 min vs. 9.8 min), neuroglycopenic symptoms (10.3 min vs. 9.9 min), and average total symptoms (13.0 min vs. 11.9 min)
- The glucagon pen more quickly resolved global hypoglycemia symptoms than the GEK (11.6 min vs. 13.1 min).
- The overall incidence of all adverse events (AEs) was comparable in both groups.

### **An Assessment of Usability and Drug Preparation Time for a Ready-to-use Liquid Glucagon Pen ([Poster CUMM1831D](#))**

Multiple evaluations have been conducted to evaluate the preparation time of the Xeris glucagon pen in comparison to the currently available GEK in controlled settings. The assessments consisted of a simulated-use human factors study with 16 first responders and caregivers of diabetic patients and a validation study among 75 adults and adolescent caregivers both experienced and new to these systems. In addition, a comparison of study drug preparation time was conducted during the Phase 3 clinical trial of the glucagon pen vs. GEK among adults with type 1 diabetes. These evaluations support the use of the glucagon pen as an alternative to currently available options and validate that it can be used correctly, safely and effectively by its intended users. Data from the studies find:

1. A significantly higher success rate delivering the full glucagon dose during simulated emergencies among both trained and untrained users:
  - In the formative usability study, 14 of 16 participants (87.5%) successfully administered a complete injection using the glucagon pen vs. 5 of 16 (31.3%) using the GEK.
  - In the summative human factors study, 74 of 75 (98.7%) participants successfully administered the glucagon pen.
2. A significant improvement in preparation time when using the glucagon pen vs. GEK:
  - Mean total administration time in the formative usability study was 47.9 seconds with the glucagon pen vs. 109.0 seconds with GEK.
  - In the Phase 3 study, drug preparation and administration time by trained healthcare professionals was significantly shorter for the glucagon pen (27.3 seconds) vs. GEK (97.2 seconds).

### **Ready-to-use Liquid Glucagon Pen – a Phase 3 Study of Plasma Glucose Recovery in Pediatric Patients with Type 1 Diabetes (T1D) ([Poster BUCK1828D](#))**

This Phase 3 clinical study was conducted to evaluate the Xeris glucagon pen for the treatment of hypoglycemia in 31 pediatric patients with type 1 diabetes. Three cohorts were studied with pre-measured pediatric doses of glucagon, dosed when plasma glucose levels reached below 80 mg/dL (ages 2 to <6 and 6 to <12 years received 0.5 mg; adolescents ages 12 to <18 years received 0.5 and 1 mg doses on two separate visits). The glucagon pen consistently corrected hypoglycemia in the study population and was safe and well tolerated. Highlights of the data show:

- All evaluable participants had a glucose elevation of  $\geq 25$  mg/dL from baseline. The mean increase in glucose at 15 minutes was 23.3 mg/dL, and at 20 minutes was 42.2 mg/dL.
- No notable differences occurred in clinical parameters (such as mean glucose AUC, C<sub>max</sub> or T<sub>max</sub>) among the age groups.

### **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](http://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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