Xeris Pharmaceuticals Announces Additional Positive Outcomes from a Global Phase 3 Clinical Trial of Its Investigational Ready-to-Use Glucagon

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Findings will support application for European marketing authorization and augment body of data supporting efficacy and utility of its ready-to-use, stable liquid glucagon

CHICAGO--(BUSINESS WIRE)--Jun. 17, 2019-- 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 positive findings from a global Phase 3 trial of its ready-to-use (RTU) room-temperature stable liquid glucagon conducted in Europe and North America.

The Phase 3, multi-center, randomized controlled, non-inferiority study was conducted among 132 adults with type 1 diabetes to evaluate the Xeris RTU glucagon auto-injector as a treatment for severe hypoglycemic events as compared with Novo Nordisk's GlucaGen® HypoKit®. The results demonstrated comparable efficacy between the two groups for achieving a plasma glucose of >70 mg/dl or ≥20 mg/dl increase in plasma glucose concentration within 30 minutes of glucagon administration. The study also found that time to resolution of hypoglycemia symptoms as well as time to resolution of the overall feeling of hypoglycemia was comparable between Xeris RTU glucagon and the marketed emergency kit. Overall, no safety or tolerability concerns were noted. (EudraCT Number 2018-002661-19, NCT03738865)

"As the population with Type 1 diabetes continues to grow in Europe, we need to ensure that patients and caregivers are equipped with effective, rapid-onset and easily administered solutions during potentially severe episodes of hypoglycemia," said Thomas Pieber, MD, Professor of Medicine, Chair of the Division of Endocrinology and Diabetology at the Medical University of Graz in Austria, and lead investigator of the study. "Based on the results of this study, the Xeris ready-to-use, stable liquid glucagon may be an effective alternative to current options to effectively control these events, giving confidence to patients and their caregivers that they can quickly intervene during emergency settings."

"This is our fourth Phase 3 trial with Xeris' ready-to-use glucagon. It provides further support of the effectiveness and utility of our ready-to-use glucagon candidate, demonstrating again that it provides an effective alternative to currently available options for severe hypoglycemia. We are confident in the profile of this treatment based on the rich data we've collected over the course of multiple trials," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We also have a number of ongoing clinical trials to evaluate our liquid stable glucagon in other important potential indications."

A New Drug Application (NDA) for the investigational product, to be branded as the Gvoke HypoPen™ in the US, is currently under review with the U.S. Food and Drug Administration (FDA), with a decision expected September 10, 2019.

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, 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.

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 Annual Report on Form 10-K 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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