

Xeris Pharmaceuticals Presents New Clinical and Economic Impact Data on Its Developmental Ready-to-Use Glucagon

March 25, 2019

Data from a Phase 2 study in congenital hyperinsulinism (CHI) shared at ENDO 2019 and a budget impact model presented at AMCP reinforce the utility of Xeris' ready-to-use, liquid-stable glucagon

CHICAGO--(BUSINESS WIRE)--Mar. 25, 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 it is presenting data on its developmental ready-to-use (RTU) room-temperature stable liquid glucagon at two medical conferences.

"Our R&D efforts continue to provide support for the value of our novel formulation technology platform for not only patients and providers, but for payers and healthcare systems as well," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We continue to advance our pipeline to understand additional potential applications for our ready-to-use, room-temperature stable liquid glucagon, particularly in high-needs areas like congenital hyperinsulinism, in which proper glucose supplementation is critical to prevent severe hypoglycemia and neurologic injury in very young patients."

ENDO 2019: A Phase 2 Comparison of a Stable Liquid Glucagon to Placebo for the Treatment of Congenital Hyperinsulinism (Session P11: SAT-272)

Xeris will present the first data from its Phase 2 study of RTU, room-temperature stable liquid glucagon for congenital hyperinsulinemia (CHI) during ENDO 2019, the Endocrine Society's annual meeting, March 23-26 in New Orleans, LA. As part of this randomized, placebo-controlled study, five patients with CHI under 1 year of age were enrolled to receive Xeris' RTU glucagon delivered continuously through an Omnipod® infusion pump to prevent hypoglycemia and to lower supplemental glucose requirements, via reductions in intravenous glucose infusion rates (GIR). Treated patients had a positive clinical response compared to those receiving placebo, and follow-up open-label treatment resulted in a clinically meaningful response in all evaluable patients.

The full data will be shared during an oral presentation scheduled for March 23, 1:00-3:00 pm CDT.

AMCP: "A Ready-To-Use Liquid Glucagon Rescue Pen for Severe Hypoglycemia Demonstrates Reduced Healthcare Payer Costs in a Budget Impact Model." (Abstract E11, Published in <u>JMCP Supplement</u>)

Results of a Xeris budget impact model on the estimated potential reduction in costs associated with use of its RTU room-temperature stable liquid glucagon will be presented in a poster during the Academy of Managed Care Pharmacy's AMCP Managed Care & Specialty Pharmacy Annual Meeting, March 25-28 in San Diego, CA. The model was developed to estimate the economic impact of open coverage of Gvoke HypoPen[™] (Xeris' ready-to-use, room-temperature stable liquid glucagon in an auto-injector) for the treatment of severe hypoglycemia events as an alternative to currently marketed glucagon emergency kits (GEKs). With its positive functional efficacy profile, the results of the model illustrate the potential financial benefits for open coverage of glucagon rescue pen (GRP). The health utilization data also supports physicians to increase patient access to completed and filled glucagon prescriptions, in order to optimize patient outcomes. Results of the analysis indicate that significant overall cost savings may be achieved with use of the Xeris GRP.

A New Drug Application (NDA) for Xeris' lead product candidate, Gvoke HypoPen[™] for the treatment of severe hypoglycemia, is currently under review with the U.S. Food and Drug Administration (FDA), with a decision expected during Q2 2019.

Omnipod® is a registered trademark of Insulet Corporation.

About Congenital Hyperinsulinism (CHI)

CHI is a very rare genetic disorder that affects 1 in 25,000 to 50,000 babies. It causes insulin cells of the pancreas, called beta cells, to secrete too much insulin. Excess insulin causes low plasma sugar (hypoglycemia). Common symptoms include irritability, sleepiness, lethargy, excessive hunger, and rapid heart rate. CHI can cause persistent hypoglycemia in newborn babies and children. Hypoglycemia can be very dangerous because the brain needs a constant source of sugar. If the brain doesn't get the sugar it needs, prolonged and extremely low blood sugar (severe hypoglycemia) can lead to seizures, coma, brain damage, and possibly 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 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 <u>www.xerispharma.com</u>.

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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