Xeris Pharmaceuticals Provides a Business Update During Recent Investor Conference

November 21, 2019

MAA submitted to EMA of liquid stable glucagon for severe hypoglycemia
GVOKE ™ PFS launch underway
GVOKE HypoPen ™ expected to launchJuly 2020
CHI program shifts to Expanded Access
HAAF program discontinued based on Phase 2 results

CHICAGO, Nov. 21, 2019 (GLOBE NEWSWIRE) -- 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 that Paul R. Edick, Xeris' Chairman and CEO, provided an update of its portfolio programs during a fireside chat at the Jefferies London Healthcare Conference. A replay of Mr. Edick's remarks is available on the Company's website.

"Today I provided recent progress on several of our programs, including the submission of our MAA to the European Marketing Agency for our ready-to-use glucagon, strong community response to our Gvoke PFS in just the first two weeks of our launch, and more definitive timing of our Gvoke HypoPen availability. I also shared the business rationale for the discontinuation of two subcutaneous continuous infusion glucagon programs, each with its own unique circumstance," said Paul R. Edick, Xeris' Chairman and CEO. "With additional clinical program data readouts in the near future and the continued enthusiasm around Gvoke, I remain excited about our prospects and momentum heading into 2020."

Liquid Stable Glucagon for Severe Hypoglycemia
Xeris recently submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its liquid stable glucagon for the treatment of severe hypoglycemia in people with diabetes, to be delivered via pre-filled syringe or auto-injector routes of administration.

The submission is based on the positive results from a Phase 3, multi-center, randomized controlled, non-inferiority study, which were presented earlier this year. The study was conducted among 132 adults with type 1 diabetes in Europe and North America to evaluate the liquid stable glucagon auto-injector as a treatment for severe hypoglycemic events as compared with Novo's GlucaGen HypoKit.

The results demonstrated comparable efficacy between the two groups in achieving a plasma glucose of >70 mg/dl or ≥20 mg/dl increase in plasma glucose concentration within 30 minutes of 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. No safety or tolerability concerns were noted. In this study, the most common adverse reactions were nausea, vomiting, and headache.

If approved, the Company could launch its RTU glucagon in certain European countries in 2021.

GVOKE™
Xeris launched Gvoke Prefilled Syringe (PFS), its liquid stable glucagon, with its 80-person field team the week of November 11, 2019. Wholesale and retail availability for Gvoke PFS was completed the week of November 4, 2019. The Company anticipates approximately 60% of lives covered by year-end. Xeris continues to be encouraged by the growing focus and dialogue about glucagon within the diabetes community, driven by new product entrants.

Additionally, Xeris announced today that it expects Gvoke HypoPen, its liquid stable glucagon in an auto-injector, to be available in commercial quantities July 2020.

Congenital Hyperinsulinism (CHI)
Xeris has decided to not proceed with a planned Phase 3 CHI study based on the challenging regulatory pathway coupled with the limited market opportunity. Instead, the Company will consider requests to make its liquid stable glucagon available for approved Expanded Access requests at no cost to eligible patients. *(Expanded Access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational drug for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.)*

Hypoglycemia Associated Autonomic Failure (HAAF)
Xeris announced today that it has concluded its Hypoglycemia Associated Autonomic Failure (HAAF) program as no statistically significant differences between the treatment arms were observed based on percent change in plasma epinephrine concentration from baseline.

In previous publications, the strict avoidance of hypoglycemia in subjects with HAAF has been shown to improve counterregulatory epinephrine and autonomic symptom responses and consequently reestablish the awareness of hypoglycemia. Xeris evaluated whether two dose levels of continuous subcutaneous glucagon infusion (CSGI), administered over 28 days, could similarly restore the epinephrine response to hypoglycemia in subjects with HAAF.

This was a Phase 2 prospective, randomized, placebo-controlled, double-blind, parallel trial in adult T1D subjects. Forty-nine subjects with documented HAAF were randomized to receive 4 weeks of treatment with high rate CSGI (n=15), low rate CSGI (n=18), or placebo (n=16). Epinephrine was quantified following a stepwise hypoglycemia induction.

CSGI was not sufficient to restore defective glucose counter-regulation (epinephrine response) or hypoglycemia symptom awareness. While there were positive epinephrine and improved hypoglycemia awareness responses observed in some subjects, the equivocal efficacy results observed may be explained by the incomplete elimination of time spent with hypoglycemia.

The administration of both low and high rate CSGI was safe and well tolerated and no SAEs related to CSGI were reported.

Additional data analyses of the study are on-going and will be presented at a future medical meeting

(HAAF is a condition marked by impairment of epinephrine secretion in response to hypoglycemia that leads to the inability to increase endogenous glucose production (defective glucose counter regulation) and the lack of autonomic symptom generation (hypoglycemia unawareness). This condition leaves the individual physiologically defenseless against hypoglycemia.)

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 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 conditions to prevent or manage various forms of hypoglycemia and improve glucose control.

About Xeris Pharmaceuticals, Inc.
Xeris (Nasdaq: XERS) is a specialty pharmaceutical company delivering innovative solutions to simplify the experience of administering important therapies that people rely on every day around the world. With a novel technology platform that enables ready-to-use, room-temperature stable formulations of injectable and infusible therapies, the company is advancing a portfolio of solutions in various therapeutic categories, including its first commercial product, Gvoke™. Its proprietary XeriSol™ and XeriJect™ formulation technologies have the potential to offer distinct advantages ove conventional product formulations, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. With Xeris' technology, new product formulations are designed to be easier to use by patients, caregivers, and health practitioners and help reduce costs for payers and the healthcare system.

Xeris is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on Twitter, LinkedIn or Instagram.

Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements regarding the acceptance of Gvoke™ in the marketplace, the market and therapeutic potential of its product candidates, expectations regarding clinical data, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, expectations regarding the timing of the commercial launch of Gvoke HypoPen, 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, its reliance on a single source supplier for Gvoke HypoPen 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.

Xeris Investor Contact
Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com
312-736-1237

Source: Xeris Pharmaceuticals, Inc.