European Medicines Agency Grants Orphan Drug Designation for Xeris' Investigational Ready-to-Use Glucagon for the Treatment of Non-Insulinoma Pancreatogenous Hypoglycaemia Syndrome (NIPHS)

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CHICAGO--(BUSINESS WIRE)--Dec. 20, 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, announced today that it has received Orphan Medicinal Product designation from the European Medicines Agency (EMA) for its investigational ready-to-use liquid glucagon as a treatment for non-insulinoma pancreatogenous hypoglycaemia syndrome (NIPHS), a spectrum of metabolic conditions, which includes post-bariatric hypoglycemia (PBH). A similar orphan designation was granted by the United States Food and Drug Administration (FDA) in January 2018. The EU orphan designation is associated with a 10-year commercial exclusivity for this indication.

"PBH is a challenging complication of bariatric surgery with no reliable treatment today. We are evaluating whether intermittent administration of our ready-to-use liquid glucagon may more rapidly and effectively address PBH, instead of relying upon dietary controls or medications that reduce glucose surges," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We believe our glucagon, if approved, could become a valued option to improve the management of PBH."

Xeris is initiating a Phase 2 randomized, double-blind, placebo-controlled study of its ready-to-use liquid glucagon in patients with post-bariatric hypoglycemia (NCT03770637). In this study, up to 12 patients (aged 18 – 75) will receive the Xeris ready-to-use glucagon or placebo during episodes of postprandial hypoglycemia (occurring after a meal) and will be followed for 12 weeks. The primary endpoint is blood glucose recovery levels (targeting over 70 mg/dL). Initial results are expected in the first half of 2019. For more information, visit www.clinicaltrials.gov. This study follows a separate Phase 2a study conducted with collaborators at Joslin Diabetes Center, an affiliate of Harvard Medical School. The results, which were published earlier this year, supported the continued development of this program.

About Post-Bariatric Hypoglycemia

Hypoglycemia typically does not present until two to three years after gastric bypass surgery. These hypoglycemic episodes are characterized by low blood sugars that occur two to three hours after a meal. Fasting hypoglycemia is typically not seen. The etiology seems to be excessive insulin secretion in response to the meal.

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 our ready-to-use glucagon formulation for the treatment of NIPHS, the expected timing of results from the Phase 2 PBH clinical trial, market and therapeutic potential of our product candidates, the potential utility of our 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 our product candidates, our ability to market and sell our 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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