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Xeris Pharmaceuticals Announces FDA Acceptance for Review of NDA for Its Ready-to-Use Glucagon Rescue Pen

If approved, the Xeris glucagon rescue pen would be the first ready-to-use, room-temperature stable liquid glucagon in an auto-injector to treat severe hypoglycemia

Robust clinical trial results from multiple Phase 3 studies and Human Factors studies demonstrating safety and efficacy in emergency settings support the NDA

PDUFA goal date of June 10, 2019

October 23, 2018 08:30 AM Eastern Daylight Time

CHICAGO--(BUSINESS WIRE)--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 its new drug application (NDA) for its ready-to-use, room-temperature stable liquid glucagon rescue pen for the treatment of severe hypoglycemia in people with diabetes has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of the glucagon rescue pen NDA of June 10, 2019.

“The FDA acceptance of our NDA for review, is an important milestone for Xeris. If approved, the Xeris glucagon rescue pen would be the first ready-to-use, liquid-stable glucagon in an auto-injector to treat severe hypoglycemia. Compared to the current glucagon rescue option for people with diabetes who are at risk for severe hypoglycemia, the Xeris glucagon rescue pen would eliminate the need for reconstitution and dramatically simplify the preparation and administration process,” said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. “We believe that our glucagon rescue pen has the potential to make an important difference in the lives of people with diabetes.”

The 505(b)2 NDA is based on positive results from multiple Phase 3 clinical trials of the efficacy, safety, and utility of the Xeris glucagon rescue pen auto-injector in treating severe hypoglycemia when compared with currently marketed glucagon emergency kits among adults, children and adolescents with type 1 diabetes (NCT02656069, NCT03091673, NCT03439072). Key study results illustrating the efficacy and tolerability of the glucagon rescue pen for both adults and children with diabetes were presented during the 78th Scientific Sessions of the American Diabetes Association (ADA), June 22-26, 2018.

In addition, positive data from Human Factors usability and reliability studies demonstrating the functional efficacy of the Xeris glucagon rescue pen supported the NDA submission. The results of one of these studies were presented during the Advanced Technologies and Treatments for Diabetes (ATTD) conference in February 2018.

About Severe Hypoglycemia

Glucagon is the standard of care for treating severe hypoglycemia. According to the American Diabetes Association (ADA), 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).

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.

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 rescue pen, the 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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