



Xeris Pharmaceuticals Announces Positive Phase 3 Clinical Trial Data on Its Investigational Ready-to-Use Glucagon Rescue Pen

June 25, 2018

Results of two Phase 3 studies presented at the American Diabetes Association's 78th Scientific Sessions

Outcomes of additional Phase 3 study support positive clinical profile for rescue pen

CHICAGO--(BUSINESS WIRE)--Jun. 25, 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, today announced the presentation of positive results from two of its Phase 3 clinical studies on its investigational ready-to-use, room-temperature stable liquid glucagon rescue pen during oral and poster sessions at the American Diabetes Association's (ADA) 78th Scientific Sessions, June 22-26, 2018.

The data presentations highlight the efficacy and safety data from studies of the Xeris ready-to-use glucagon rescue pen in treating severe hypoglycemia in adults and children with type 1 diabetes, as compared to the currently marketed Glucagon Emergency Kit (GEK).

In addition to the Phase 3 study results presented at the ADA conference, Xeris also generated positive data from an additional Phase 3 cross-over study of the Xeris rescue pen among adults with type 1 diabetes. In that study, all participants (100%) treated with the Xeris rescue pen achieved plasma glucose of >70 mg/dL or ≥ 20 mg/dl increase within 30 minutes of injection. There were no reported significant adverse events and adverse events were generally mild to moderate in severity, with the most common being nausea and vomiting.

"Together, the positive data from multiple studies demonstrate that our ready-to-use glucagon rescue pen has the potential to be a well-tolerated and functionally effective alternative to treat severe hypoglycemia among both adults and children with diabetes," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We look forward to advancing our program with the goal of introducing a valued new emergency intervention for the diabetes community."

A Phase 3 Comparison of a Novel Liquid Glucagon Autoinjector to Glucagon Emergency Kit for the Symptomatic Relief of Severe Hypoglycemia ([304-OR](#)) (NCT02656069)

The randomized, controlled, double-blind, cross-over clinical trial evaluated the two rescue treatments among 80 adults with type 1 diabetes to treat insulin-induced severe hypoglycemia. The study found similar speed to relief between the Glucagon Autoinjector (GAI) and the GEK for autonomic (e.g. shaking, anxiety, sweating) and neuroglycopenic (e.g. confusion, drowsiness) symptoms, as well as global feelings of hypoglycemia. The incidence of all adverse events was low in both groups.

A Phase 3 Comparison of a Novel Liquid Glucagon Autoinjector to Glucagon Emergency Kit for the Treatment of Severe Hypoglycemia ([Poster 1239](#)) (NCT02656069)

The study, conducted among 80 adults with type 1 diabetes, found the efficacy to be comparable between the two groups with 100% of patients being successfully rescued from insulin-induced hypoglycemia without other rescue therapy, and 97.4% of subjects achieving a plasma glucose of >70 mg/dl or ≥ 20 mg/dl increase within 30 minutes of glucagon (versus 100% for GEK). GAI was generally well-tolerated, with all adverse events being mild or moderate in severity.

Liquid Room Temperature Stable Glucagon—Glucose Response in Pediatric Type 1 Diabetes Patients [Poster 1241](#)) (NCT03091673)

A total of 31 pediatric patients (divided into age groups 2 to <6 years, 6 to <12 years and 12 to <18 years) participated in the Phase 3 study to evaluate two age-specific doses of the GAI (0.5 mg or 1 mg) in the treatment of hypoglycemia. All participants achieved statistically significant increases in plasma glucose levels within 30 minutes of administration, reaching an increase in mean plasma glucose levels ≥ 25 mg/dL from baseline. The rate of reported adverse events was low.

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 non-aqueous formulation 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 allow for the subcutaneous ("SC") and intramuscular ("IM") delivery of highly-concentrated, non-aqueous, ready-to-use formulations of peptides, proteins, antibodies and small molecules using commercially available syringes, auto-injectors, multi-dose pens, and infusion pumps. XeriSol™ is applicable to peptides and small molecules, whereas XeriJect™ is directed to drugs and biologics consisting of large molecules, such as therapeutic proteins, monoclonal antibodies, and vaccines.

Xeris' platforms offer the opportunity to eliminate the need for reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume, and allow for a more convenient SC or IM administration. 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 therapeutic potential of our product candidates and the potential utility of our formulation platform 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 final prospectus related to Xeris's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, as well as discussions of potential risks, uncertainties, and other important factors in Xeris's 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.

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