Xeris Pharmaceuticals Receives U.S. FDA Approval for GVOKE™ (glucagon), the First Ready-to-use Stable Liquid Glucagon for Severe Hypoglycemia

September 10, 2019

First approval for Xeris is based on positive efficacy and safety results from multiple clinical studies

GVOKE is the first premixed, prefilled, premeasured liquid glucagon offering ease of use for pediatric and adult patients with diabetes ages 2 years and above or caregivers to rapidly treat severe hypoglycemic events

Company to host conference call today at 12:30 pm ET

CHICAGO--(BUSINESS WIRE)--Sep. 10, 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, announced today that it has received regulatory approval from the U.S. Food and Drug Administration (FDA) for GVOKE™ (glucagon) injection, its ready-to-use, room-temperature stable liquid glucagon for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above.

GVOKE is the first glucagon product approved that can be administered via a prefilled syringe (GVOKE PFS) or auto-injector (GVOKE HypoPen™), vastly reducing the steps to prepare and administer glucagon in the event of severe hypoglycemia, or dangerously low blood sugar levels. These innovative formats are designed to provide the reliability of a ready-to-use liquid glucagon while making it easier for patients or caregivers to administer quickly and simply. GVOKE will be available in two doses: a 0.5 mg/0.1 mL dose for pediatric patients and a 1 mg/0.2 mL dose for adolescent and adult patients. GVOKE is contraindicated in patients with pheochromocytoma, insulinoma, and patients with a known hypersensitivity to glucagon or to any of the excipients in GVOKE.

“Everyone managing diabetes is at risk for developing severely low blood sugar, or hypoglycemia, and we know this can quickly progress from a mild event to an emergency situation. The availability of GVOKE - the first ready-to-use liquid glucagon option - brings confidence to patients, parents and caregivers that these challenging events can be easily and rapidly resolved,” said Davida Kruger, MSN, APN-BC, BC-ADMCertified Nurse Practitioner, Henry Ford Health System, Division of Endocrinology, Diabetes and Bone Disorders, Detroit, Michigan.

The FDA's approval is based on positive results from three Phase 3 clinical trials evaluating the efficacy, safety, and utility of GVOKE in treating severe hypoglycemia when compared with conventional glucagon emergency kits among adults and children with type 1 diabetes (NCT02656069, NCT03091673, NCT03439072). The studies demonstrated 100% treatment success in children and 99% treatment success in adults. Usability research evaluating the GVOKE PFS and GVOKE HypoPen demonstrated nearly 100% success rates in administering a full dose of glucagon using the simple 2-step administration process. The most common adverse reactions in adults were nausea, vomiting, injection site edema, and headache. In pediatric and adolescent patients, the most common adverse reactions were nausea, hypoglycemia, vomiting, headache, abdominal pain, hyperglycemia, injection site reactions and discomfort, and urticaria. Approximately 80% of side effects seen were mild.

"Until now, many people may have been hesitant to use conventional glucagon kits because the complex preparation felt confusing and perhaps overwhelming. With GVOKE as a new glucagon option, we gain an easy to use and effective solution to a dangerous and stressful event," said Jeff Hitchcock, founder and president of Children with Diabetes.

"The approval of GVOKE is an important step forward for people with diabetes. Severe hypoglycemia is a terrifying and dangerous diabetes complication. This new option will make treatment easier and faster in the event of an emergency,” said Aaron J. Kowalski, Ph.D., President and CEO of JDRF.

“While we celebrate this approval as Xeris’ first commercial product, more importantly, this milestone is a positive step forward for the diabetes community as the first premixed, prefilled, and premeasured liquid glucagon to effectively treat severe hypoglycemia in both adults and children with diabetes,” said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. “We are actively preparing to introduce GVOKE in two different administration options to accommodate the community’s preferences starting with our pre-filled syringe in 4-6 weeks and the auto-injector in 2020.”

Conference Call Details

Xeris Pharmaceuticals will host a conference call and webcast today, Tuesday, September 10, 2019 at 12:30 pm Eastern Time. The conference call can be accessed by dialing 866-951-8137 for domestic callers and 270-215-9500 for international callers. Please provide the operator with the conference ID 6588821 to join the conference call. The conference call will be available via webcast under the Investors section of Xeris' website at www.xerispharma.com. An archive of today's webcast will be available on Xeris’ website for 60 days following the call.

Indication

GVOKE™ is indicated for the treatment of severe hypoglycemia in patients with diabetes ages 2 years and above.

Important Safety Information

Contraindications

GVOKE is contraindicated in patients with pheochromocytoma, insulinoma, and known hypersensitivity to glucagon or to any of the excipients in

GVOKE. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

Warnings and Precautions

- GVOKE is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumor. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.
- In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, GVOKE administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. GVOKE is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of GVOKE, give glucose orally or intravenously.
- Allergic reactions have been reported with glucagon. These include generalized rash, and in some cases, anaphylactic shock with breathing difficulties and hypotension. GVOKE is contraindicated in patients with a prior hypersensitivity reaction.

GVOKE is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycemia, may not have adequate levels of hepatic glycogen for GVOKE administration to be effective. Patients with these conditions should be treated with glucose.

Adverse Reactions

Most common (≥10%) adverse reactions associated with GVOKE are nausea, vomiting, and hypoglycemia.

Drug Interactions

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given GVOKE. In patients taking indomethacin, GVOKE may lose its ability to raise blood glucose or may even produce hypoglycemia. GVOKE may increase the anticoagulant effect of warfarin.

Please see full Prescribing Information for GVOKE PFS and GVOKE HypoPen on www.xerispharma.com. Manufactured for Xeris Pharmaceuticals, Inc. by Pyramid Laboratories Inc., Costa Mesa, CA 92626.

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 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 commercial supply of GVOKE™, 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 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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