Xeris Pharmaceuticals Receives European Commission Approval of Ogluo™ (glucagon) Injection for the Treatment of Severe Hypoglycaemia in Adults, Adolescents, and Children Aged 2 Years and Over With Diabetes Mellitus

February 12, 2021

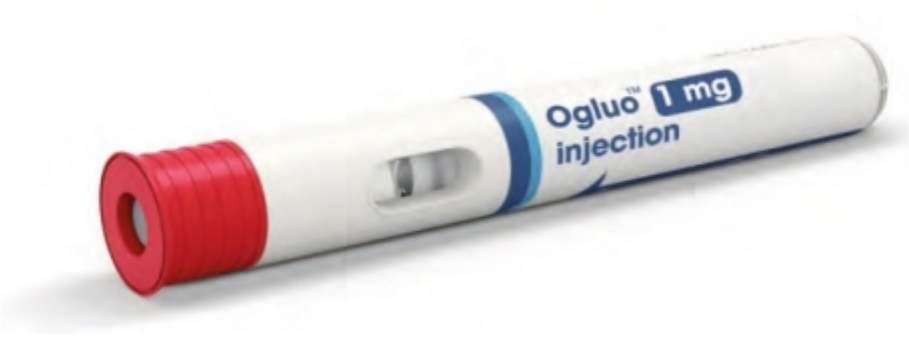
OGLUO™ Europe's first and only ready-to-use liquid glucagon for rescue

First availability expected in the fourth quarter

Approval supported by data from pivotal Phase 3 study

CHICAGO & DUBLIN--(BUSINESS WIRE)--Feb. 12, 2021-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced that the European Commission (EC) has approved Ogluo™ (glucagon) injection for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus. The marketing authorisation is valid in all 27 countries of the European Union, plus Iceland, Norway, and Liechtenstein. As the EC decision was received after the end of the Brexit transition period, Xeris will complete a further administrative step in order to obtain a license in Great Britain. No re-examination of clinical data by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) is expected.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210212005054/en/



(Photo: Business Wire)

"This EU approval for Ogluo is a major milestone for Xeris and a significant advancement in the treatment of severe hypoglycaemia for the diabetes community in Europe. Hypoglycaemia is the #1 side effect of insulin, and severe hypoglycaemia is the most urgent emergency any person with diabetes could face. Ogluo, the first pre-mixed auto-injector for severe hypoglycaemia, can help offset the inherent risk associated with insulin," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We are preparing to launch Ogluo later this year, while simultaneously seeking a commercialization partner in which to broaden the availability of Ogluo to more European countries."

The EC approval was supported by data from a Phase 3, multi-centre, randomized controlled, non-inferiority study. 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 hypoglycaemic events compared with Novo Nordisk's GlucaGen ® HypoKit®. The results demonstrated comparable efficacy between the two groups in achieving a plasma glucose of greater than 3.89 mmol/L (>70 mg/dL) or a relative increase of 1.11 mmol/L (≥20 mg/dL) in plasma glucose concentration within 30 minutes of administration. The study also found that time to resolution of hypoglycaemia symptoms as well as time to resolution of the overall feeling of hypoglycaemia were comparable. No safety or tolerability concerns were noted. In this study, the most common adverse reactions were nausea and vomiting.

"Hypoglycaemia is a neglected complication of glucose-lowering therapy in patients with diabetes mellitus. Attempts made at intensive glycaemic control invariably increases the risk of hypoglycaemia. In patients experiencing severe hypoglycaemia an increase in deaths up to six-fold has been associated to diabetes in comparison to those not experiencing severe hypoglycaemia. Patients with diabetes should be evaluated for the risk of clinically important hypoglycaemia and have access to ready-to-use glucagon," said Thomas Pieber, MD, Professor of Medicine, Chair, Division of Endocrinology and Diabetology, Department of Internal Medicine, Medical University of Graz, Austria.

ABOUT GVOKE/OGLUO

Gvoke® PFS and Gvoke HypoPen® (glucagon injection), the first prescription, ready-to-use, pre-mixed, pre-measured glucagon injection, were approved by the FDA in September 2019 for use in the United States. Gvoke is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. Ogluo received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in December 2020 and the European Commission (EC) granted the marketing authorisation on 11 February 2021. Ogluo is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR GVOKE

Gvoke is indicated for the treatment of severe hypoglycaemia in adult and paediatric 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.

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas has been reported post-marketing following continuous glucagon infusion and resolved with discontinuation of the glucagon. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks. Glucagon administered to patients with glucagonoma may cause secondary hypoglycemia.

Adverse Reactions

Most common (≥5%) adverse reactions associated with Gvoke are nausea, vomiting, injection site edema (raised 1 mm or greater), and hypoglycemia.

Drug Interactions

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given OGLUO. 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 on www.xerispharma.com. Manufactured for Xeris Pharmaceuticals, Inc. by Pyramid Laboratories Inc., Costa Mesa, CA 92626.

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 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 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 U.S. commercial product, Gvoke®. Its proprietary XeriSol™ and XeriJect™ formulation technologies have the potential to offer distinct advantages over 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 market and therapeutic potential of its products and product candidates, expectations regarding clinical data or results from planned clinical trials, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, the timing or likelihood of identifying potential development and commercialization partnerships, 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 impact of COVID-19 on its business operations, its reliance on third-party suppliers for Gvoke® and Ogluo™, 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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Xeris Investor Contact
Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com
312-736-1237

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