



Xeris Pharmaceuticals Receives U.K. MHRA Approval of Ogluo® (glucagon) Injection for the Treatment of Severe Hypoglycaemia in Adults, Adolescents, and Children Aged 2 Years and Over With Diabetes Mellitus

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CHICAGO & DUBLIN--(BUSINESS WIRE)--Apr. 29, 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 United Kingdom's Medicines and Healthcare Regulatory Agency (MHRA) has approved Ogluo® (glucagon) injection for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

In February, the European Commission (EC) approved Ogluo. As the EC decision was received after the end of the Brexit transition period, Xeris was required to complete a further administrative step in order to obtain a license in Great Britain. No re-examination of clinical data by MHRA was required. The marketing authorization is valid in the United Kingdom, all 27 countries of the European Union, Iceland, Norway, and Liechtenstein.

As previously stated, the Company is actively seeking a partner to commercialize Ogluo in the U.K., EU, and other regions, with a targeted fourth quarter 2021 launch in select EU countries.

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 authorization 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20210429006009/en/>

Xeris Investor Contact

Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com
312-736-1237

Source: Xeris Pharmaceuticals, Inc.