Xeris Pharmaceuticals Announces Approval of Supplemental New Drug Application (sNDA) of Gvoke® Kit for the Treatment of Severe Hypoglycemia

August 23, 2021

First ready-to-use liquid glucagon available in a single-dose vial and syringe kit for rescue

Gvoke HypoPen®, Gvoke® PFS, and Gvoke® Kit – three different administration options to accommodate patients' preferences

Gvoke Kit eliminates the need for reconstitution

Gvoke Kit availability anticipated in early Q1 2022

CHICAGO--(BUSINESS WIRE)--Aug. 23, 2021-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use injectable drug formulations, today announced that its supplemental new drug application (sNDA) of Gvoke® Kit was approved by the Food and Drug Administration (FDA) for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. Gvoke Kit will be available as a 1 mg/0.2 mL single dose vial and syringe kit. Gvoke Kit contains one (1) single-dose sterile syringe with markings for 0.1 mL (0.5 mg pediatric dose) and 0.2 mL (1 mg adult dose), and one single-dose vial containing 0.2 mL of solution. With this FDA approval, Xeris will begin manufacturing scale up immediately, and therefore anticipates Gvoke Kit availability early in the first quarter of 2022.

"Offering three different administration options - Gvoke HypoPen®, Gvoke® PFS, and Gvoke ® Kit, allows for greater patient choice in a ready-to-use rescue product for the approximately 6.8 million people in the U.S. who rely on insulin and are at-risk of a severe hypoglycemic event. These innovative formats provide the reliability of a ready-to-use liquid glucagon while offering multiple administration options for patients and caregivers," said Paul R. Edick, Chairman and CEO of Xeris. "In particular for patients or caregivers who prefer to draw up their Gvoke rescue dose using a vial and syringe, Gvoke Kit reduces the number of steps by eliminating reconstitution - the most common mistake in correctly administering the conventional glucagon kit."

The sNDA approval was supported by a pharmacokinetic study demonstrating bioequivalence of a 1 mg Gvoke dose administered via a vial and syringe kit (Gvoke Kit) to that of 1 mg Gvoke administered as a pre-filled syringe (Gvoke PFS).

ABOUT Gvoke® (US) /Ogluo® (EU)

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 hypoglycaemia in paediatric 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. The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) approved Ogluo® (glucagon) injection on April 29, 2021. Ogluo is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus. In August 2021, the FDA approved Gvoke Kit, the first ready-to-use glucagon available in a single-use vial and single-use syringe kit for rescue.

INDICATION AND IMPORTANT SAFETY INFORMATION

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

IMPORTANT SAFETY INFORMATION

Contraindications

GVOKE is contraindicated in patients with pheochromocytoma because of the risk of substantial increase in blood pressure, insulinoma because of the risk of hypoglycemia, 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 (glucagon-producing tumors) and characterized by scaly, pruritic erythematous plaques, bullae, and erosions, has been reported postmarketing following continuous glucagon infusion. NME lesions may affect the face, groin, perineum and legs or be more widespread. In the reported cases NME resolved with discontinuation of the glucagon, and treatment with corticosteroids was not effective. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks.

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 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 on www.xerispharma.com. Manufactured for Xeris Pharmaceuticals, Inc. by Pyramid Laboratories Inc., Costa Mesa, CA 92626.

About Xeris Pharmaceuticals, Inc.

Xeris (Nasdaq: XERS) is a 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 commercial product, Gvoke® in the U.S. 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 availability of Gvoke® Kit in the U.S. in the first quarter of 2022, the market and therapeutic potential of Gvoke HypoPen®, Gvoke® PFS, and Gvoke® Kit, the timing or likelihood of regulatory approval and commercialization of Gvoke® Kit 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 Gvoke® Kit, 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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