Xeris Biopharma Announces Gvoke® Kit Is Now Available for the Treatment of Severe Hypoglycemia in Adults and Children With Diabetes Ages 2 And Above

March 16, 2022

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

CHICAGO--(BUSINESS WIRE)--Mar. 16, 2022-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology, and gastroenterology, today announced that Gvoke® (glucagon injection) Kit is now available by prescription. 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.

“We are pleased to offer another ready-to-use rescue form of Gvoke for the millions of people with diabetes at increased risk of a severe low blood sugar event. Gvoke Kit contains the same room-temperature liquid-stable glucagon as in Gvoke HypoPen® and Gvoke® PFS but may be preferred by those who would rather draw up the appropriate rescue dose using a vial and syringe,” said Kevin McCulloch, Xeris’ Chief Commercial Officer. “Awareness of the benefits to patients of having their Gvoke nearby is growing quickly, and we expect availability of Gvoke Kit to add to the growing interest.”

ABOUT Gvoke®

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. 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

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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 Biopharma

Xeris (Nasdaq: XERS) is a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology, and gastroenterology. Xeris has three commercially available products; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, Keveyis®, the first and only FDA-approved therapy for primary periodic paralysis, and Recorlev® for the treatment of endogenous Cushing's syndrome. Xeris also has a robust pipeline of development programs to extend the current marketed products into important new indications and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect™, supporting long-term product development and commercial success.

Xeris Biopharma Holdings 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 Biopharma, including statements regarding the availability of Gvoke® Kit in the U.S., the market and therapeutic potential of Gvoke HypoPen®, Gvoke® PFS, and Gvoke® Kit, the timing 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® , 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 Xeris' Annual Report on Form 10-K 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/20220316005150/en/

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