Xeris Ships One Millionth Gvoke® Unit

July 31, 2023

Updated guidelines recognize the benefits of ready-to-use glucagon

Protecting all people with diabetes at risk of severe hypoglycemia remains the goal

CHICAGO--(BUSINESS WIRE)--Jul. 31, 2023-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing innovative products across a range of therapies, today announced that Xeris has shipped more than one million units of Gvoke® – the company's ready-to-use liquid glucagon for the treatment of severe hypoglycemia in adults and children with diabetes ages 2 years and above.

"We are proud to celebrate this major milestone of having shipped over one million units of Gvoke since its launch," said Paul R. Edick, Xeris' Chairman and CEO. "However, far too many people with diabetes are still left without protection against a potentially life-threatening severe low blood sugar event. Based on recently updated guidelines by the American Diabetes Association[1] and others, we estimate that approximately 15 million people[2] with diabetes are at increased risk of low blood sugar, a primary risk factor being on insulin, and should be carrying a ready-to-use glucagon, like Gvoke HypoPen®," Mr. Edick continued, "We will continue to work tirelessly towards our mission of protecting as many of the 15 million as possible and call on the medical community to take responsibility to make these new standards of care your standards of practice."

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

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

Xeris (Nasdaq: XERS) is a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing differentiated and innovative products across a range of therapies. Xeris has three commercially available products: Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia; Keveyis®, a proven therapy for primary periodic paralysis; and Recorlev® for the treatment of endogenous Cushing's syndrome. Xeris has a diverse pipeline of development and partnered programs using its formulation sciences, XeriSol™ and XeriJect™, to support 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 Holdings, Inc., including the market and therapeutic potential of Gvoke®, the potential utility of its formulation platforms and other statements containing the words "will," "would," "continue," "expect," "anticipate," "estimate" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris' experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, geopolitical factors and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The various factors that could cause Xeris' actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, include its financial position and need for financing, including to fund its product development programs or commercialization efforts, whether its products will achieve and maintain market acceptance in a competitive business environment, its reliance on third-party suppliers, including single-source suppliers, its reliance on third parties to conduct clinical trials, the ability of its product candidates to compete successfully with existing and new drugs, and its and collaborators' ability to protect its intellectual property and proprietary technology. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Xeris can be found in Xeris' filings, including its most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to us, as of the date of this communication and, while believed to be reasonable, actual results may differ materially. Subject to any obligations under applicable law, we do not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

1. American Diabetes Association, *Diabetes Care*, 2023;46(suppl 1):S97-S110
2. Xeris internal estimate

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