Xeris' Commercialization Partner for Ogluo®, Tetris Pharma Ltd, to Be Acquired by Arecor Therapeutics

August 1, 2022

Tetris will be acquired by Arecor and continue to commercialize Ogluo in the UK and EEA

CHICAGO--(BUSINESS WIRE)--Aug. 1, 2022-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology and neurology, today announced that Tetris Pharma—its commercialization partner for Ogluo in the UK, EEA, and Switzerland—will be acquired by Arecor Therapeutics (AIM: AREC), a UK-based, publicly traded, globally focused biopharmaceutical company, contingent upon a successful capital offering by Arecor Therapeutics. Under the terms of the proposed acquisition, Arecor Therapeutics has agreed to acquire Tetris Pharma and will continue to commercialize Ogluo in the UK and EEA.

"We look forward to working with Arecor as our commercial partner if the proposed acquisition is completed. Arecor is a diversified and well capitalized company with a key focus on the diabetes space. Having our ready-to-use glucagon, Ogluo, commercialized in the UK and EEA by Arecor would be a very positive step forward in our view," said Paul R. Edick, Xeris' Chairman and CEO. "We are working expeditiously with Tetris and Arecor to affect a smooth transition of commercial activities and will continue to support the commercial efforts going forward."

In July 2021, Xeris announced an exclusive agreement with Tetris Pharma Limited ("Tetris") for the commercialization of Ogluo® in the European Economic Area, United Kingdom, and Switzerland (the "Territory") for the treatment of severe hypoglycemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus. Under the terms of the applicable agreements, Xeris is responsible for product supply and Tetris is responsible for the commercialization of Ogluo in the Territory. Tetris Pharma has, conditional upon completion of the Acquisition, entered into an amendment to its exclusive 16-year minimum term license and supply agreements with Xeris for the sale and distribution of Ogluo® in the EEA, UK, and Switzerland. Pursuant to the license, a mid-single-digit royalty on net sales is payable to Xeris over the license period. In addition, further one-off commercial milestone payments are payable to Xeris in the event that net revenues exceed pre-defined targets in any single calendar year.

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 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. 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.

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 tumour. 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 hypoglycaemia. Gvoke is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycaemia 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 hypoglycaemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycaemia, 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 hypoglycaemia.

Adverse Reactions

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

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 hypoglycaemia. 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 (hypoglycaemia), is also prevalent in this population due to dysregulated glucagon secretion. Severe hypoglycaemia 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 hypoglycaemia. According to the American Diabetes Association, glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycaemia, defined as blood glucose <54 mg/dL (3.0 mmol/L). Leveraging XeriSol™, one of Xeris' two proprietary formulation technology platforms, Xeris was able to develop 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 hypoglycaemia and improve glucose control.

About Severe Hypoglycaemia

Hypoglycemic events of any severity are a daily concern for people with diabetes. Mild or moderate hypoglycaemia can occur multiple times a month. Severe hypoglycaemia is characterized by severe cognitive impairment, requiring external assistance for recovery, and can be extremely frightening for patients and caregivers. Severe hypoglycaemia 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

Xeris (Nasdaq: XERS) is a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology and neurology. 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 Holdings, Inc. including statements regarding the market and therapeutic products and product candidates, the potential or likelihood of future payments under the Tetris Agreement, the timing or likelihood of expansion into additional markets, including, the EEA, future performance of Tetris under the Tetris Agreement and anticipated results and potential benefits of the commercialization partnership, , the potential utility of its formulation platforms, the timing or effects of the potential acquisition of Tetris 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. 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, 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 factors described in the context of such forward-looking statements in this communication 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. Although it is believed that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this communication are therefore cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this communication. Additional information about economic, competitive, governmental, technological, and other factors that may affect Xeris is set forth in the "Risk Factors" section of the 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. Any forward-looking statements in this communication are based upon information available to Xeris, as of the date of this communication and, while believed to be true when made, may ultimately prove to be incorrect. Subject to any obligations under applicable law, Xeris does 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. All subsequent written and oral forward-looking statements attributable to Xeris or any person acting on behalf of any of them are expressly qualified in their entirety by this paragraph.

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Source: Xeris Biopharma Holdings, Inc.