Xeris Announces Approval of Supplemental New Drug Application (sNDA) of Gvoke VialDx™ (glucagon) for Use as a Diagnostic Aid

March 17, 2025

First concentrated, ready-to-dilute liquid glucagon available for growing procedural gastroenterology market

American Regent to commercialize GVOKE VialDx ™

Availability is expected in the third quarter of 2025

CHICAGO--(BUSINESS WIRE)--Mar. 17, 2025-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, today announced that its supplemental new drug application (sNDA) of Gvoke VialDx™ has receivedJ.S Food and Drug Administration (FDA) approval for use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.

Xeris also announced it has partnered with American Regent to commercialize Gvoke VialDx. Under the terms of the agreement, Xeris will be responsible for product supply, and American Regent will be responsible for the commercialization of Gvoke VialDx in the U.S. Financial terms were not disclosed.

“We’re excited about the approval of Gvoke VialDx and our partnership with American Regent. Gvoke VialDx has the potential to modernize the handling and administration of glucagon for diagnostic procedures,” said Kevin McCulloch, President and COO of Xeris. “American Regent is the perfect partner for Gvoke VialDx given their long history as a leading provider of high quality, sterile injectable products to the hospital and acute care marketplace."

Joann Gioia, Vice President and Chief Commercial Officer at American Regent, said, “We are eager to bring our commercial expertise in the hospital and acute care setting to our partnership with Xeris and contribute to the success of Gvoke VialDx. With an estimated 20 million gastrointestinal endoscopic procedures performed annually, the addition of Gvoke VialDx to our portfolio aligns perfectly with our mission to provide patients with the essential medicines they need.”

Gvoke VialDx will be available as a 1-count or 10-count package of 1 mg per 0.2 mL single-dose vials.

Indications and Important Safety Information
Gvoke is an antihypoglycemic agent indicated for subcutaneous use for the treatment of severe hypoglycemia in adult and pediatric patients aged 2 years and older with diabetes.

Gvoke VialDx is a gastrointestinal motility inhibitor indicated for intravenous use as a diagnostic aid for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patients.

- Gvoke and Gvoke VialDx are contraindicated in patients with:
  - Pheochromocytoma because of the risk of substantial increase in blood pressure
  - Insulinoma because of the risk of hypoglycemia
  - Prior hypersensitivity reaction to glucagon or to any of the excipients. Serious hypersensitivity reactions have been reported with glucagon, including generalized rash, and anaphylactic shock with breathing difficulties and hypotension
  - Gvoke VialDx is also contraindicated in patients with glucagonoma because of risk of hypoglycemia
- Glucagon may stimulate the release of catecholamines from the tumor. If patient develops a substantial increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate 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, glucagon may stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. If a patient develops symptoms of hypoglycemia after a dose of Gvoke or Gvoke VialDx, give glucose orally or intravenously
- Patients with insufficient hepatic stores of glycogen may not respond to Gvoke for treatment of hypoglycemia. Insufficient hepatic stores of glycogen may be present in conditions such as states of starvation, or in patients with adrenal insufficiency or chronic hypoglycemia
- A skin rash called necrolytic migratory erythema (NME), has been reported post-marketing following continuous glucagon infusion and resolved with discontinuation of the glucagon. Gvoke and Gvoke VialDx are not approved for continuous infusion. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks
- Gvoke VialDx in patients with diabetes mellitus may cause hyperglycemia. Monitor diabetic patients for changes in blood glucose levels during treatment with Gvoke VialDx and treat hyperglycemia, if indicated
- Gvoke VialDx may increase myocardial oxygen demand, blood pressure, and pulse rate which may be life threatening in patients with cardiac disease. Cardiac monitoring is recommended in patients with cardiac disease during use of Gvoke

ViaIDx, and an increase in blood pressure and pulse rate may require therapy
- Gvoke ViaIDx administered to patients with glucagonoma may cause secondary hypoglycemia. Test patients suspected of having glucagonoma for blood levels of glucagon prior to treatment and monitor for changes in blood glucose during treatment
- Most common adverse reactions reported for Gvoke in adult patients were nausea, vomiting, injection site edema raised 1 mm or greater, and headache
- Most common adverse reactions reported for Gvoke in pediatric patients were nausea, hypoglycemia, vomiting, headache, abdominal pain, hyperglycemia, injection site discomfort and reaction, and urticaria.
- Most common adverse reactions reported for Gvoke ViaIDx were nausea, dysgeusia, headache, dizziness and hot flush
- Gvoke and Gvoke ViaIDx may increase the anticoagulant effect of warfarin; and in patients taking beta-blockers, may have a transient increase in pulse and blood pressure. In patients taking indomethacin Gvoke may lose its ability to raise glucose or may produce hypoglycemia. Concomitant use of anticholinergic drugs with Gvoke ViaIDx is not recommended. Monitor blood glucose when Gvoke ViaIDx is used in patients receiving insulin.

For full Prescribing Information, visit www.xerispharma.com.

About Xeris
Xeris (Nasdaq: XERS) is a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products: Recorlev®, for the treatment of endogenous Cushing's syndrome; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, and a gastrointestinal motility inhibitor when used during radiology exams as a diagnostic aid; and Keveyis®, a proven therapy for primary periodic paralysis. Xeris also has a pipeline of development programs led by XP-8121, a Phase 3-ready, once-weekly subcutaneous injection for hypothyroidism, as well as multiple early-stage programs leveraging Xeris' technology platforms, XeriSol® and XeriJect®, for its partners.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on X, LinkedIn, or Instagram.

About American Regent
American Regent, Inc., a Daiichi Sankyo Group company, is an industry leading US-based pharmaceutical company. For nearly 60 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables to healthcare providers. For more than 20 years, American Regent has been a leader in IV iron therapy supplying the market with the two top-selling brands in the US. We are committed to setting a higher standard for responsiveness, reliability, and quality and helping patients live better lives by providing the essential medicines they need is the constant motivation behind everything we do, everyday. Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, visit www.americanregent.com

Forward-Looking Statements
Any statements in this press release other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the development and potential of a glucagon diagnostic product utilizing Xeris' XeriSol™ technology, the potential for Gvoke ViaIDx to modernize the handling and administration of glucagon for diagnostic procedures, the expectations regarding future commercialization of Gvoke ViaIDx by American Regent, the timing of availability of Gvoke ViaIDx, Xeris' potential entitlements to milestone and royalty payments from American Regent, the potential utility of its formulation platforms such as XeriSol™, the market and therapeutic potential of its products and product candidates, and other statements containing the words "will," "would," "continue," "expect," "should," "anticipate" 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, but are not limited to, 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 risks and 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 Annual Report on Form 10-K 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 we believe our assumptions are 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.

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