Xeris Pharmaceuticals Receives Positive CHMP Opinion for Ogluo™, Its Ready-To-Use (RTU) Glucagon for Injection, for the Treatment of Severe Hypoglycaemia in Adults, Adolescents, and Children Aged 2 Years and Over With Diabetes Mellitus

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Positive CHMP Opinion based on data from a multi-center, randomized Phase 3 trial

CHICAGO--(BUSINESS WIRE)--Dec. 11, 2020-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation technology platforms to develop and commercialize ready-to-use (RTU) injectable and infusible drug formulations, announced that yesterday the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive Opinion for Ogluo™ (glucagon). Ogluo is the EU trade name for Xeris' RTU glucagon for injection. The CHMP recommends Ogluo for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

The European Commission will review the CHMP recommendation, and a final decision on the Marketing Authorization Application for Ogluo in the European Union (EU) is expected in the first quarter of 2021. If Ogluo is approved, the Company could launch Ogluo in certain European countries in the second half of 2021. Gvoke® PFS and Gvoke HypoPen® (glucagon injection) were approved in the U.S. in 2019 for the treatment of pediatric and adult patients with diabetes over 2 years of age.

"The positive CHMP recommendation brings us one step closer to offering a new, simple and reliable treatment for patients in Europe who are at-risk for a severe hypoglycemic event," said Paul R. Edick, Chairman and CEO of Xeris. "We look forward to the European Commission's decision and the opportunity to potentially change people's ability to confidently respond to a severe hypoglycemic event in a timely manner."

The positive Opinion received yesterday is based on the results from a Phase 3, multi-center, randomized controlled, non-inferiority study. The study was conducted among 132 adults with type 1 diabetes in Europe and North America to evaluate the liquid stable glucagon auto-injector as a treatment for severe hypoglycemic events compared with Novo Nordisk's GlucaGen® HypoKit®. The results demonstrated comparable efficacy between the two groups in achieving a plasma glucose of >70 mg/dL or ≥20 mg/dL increase in plasma glucose concentration within 30 minutes of administration. The study also found that time to resolution of hypoglycemia symptoms as well as time to resolution of the overall feeling of hypoglycemia were comparable. No safety or tolerability concerns were noted. In this study, the most common adverse reactions were nausea and vomiting.

About GVOKE®

Xeris received U.S. regulatory approval in 2019 for GVOKE® (glucagon) injection, its ready-to-use, room-temperature stable liquid glucagon for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. The Company continues to evaluate additional applications to address needs in severe hypoglycemia and related conditions. Important Safety Information and a link to full prescribing information may be found at https://www.gvokeglucagon.com.

About Xeris Pharmaceuticals, Inc.

Xeris (Nasdaq: XERS) is a specialty 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®. 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 timing of a final decision on the Marketing Authorization Application for Ogluo™ by the European Medicines Agency in the European Union, the anticipated timing of launch in Europe, the timing or likelihood of expansion into additional markets, the potential utility of its formulation platforms, and other statements containing the words "plans", "expects", "anticipates", "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 regulatory approval of its product candidates, 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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