Xeris Pharmaceuticals Granted Fast Track Designation by the FDA for Its Novel Concentrated Diazepam Formulation (XP-0863) For Injection

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CHICAGO--(BUSINESS WIRE)--Oct. 20, 2020-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced it was granted Fast Track designation by the Food and Drug Administration (FDA) for the investigation of XP-0863 (diazepam non-aqueous injection) for the treatment of acute repetitive seizures. Xeris' XP-0863 was previously granted orphan designations both for the treatment of acute repetitive seizures and for the treatment of Dravet Syndrome.

"The FDA's Fast Track designation highlights the clear unmet need in treating acute repetitive seizures with the preparations of diazepam available today and highlights our opportunity to dramatically improve care through the introduction of a ready-to-use injection formulation," said Paul R. Edick, Xeris' Chairman and Chief Executive Officer. "We are working to identify the right development and commercialization partner who can accelerate our efforts to evaluate and deliver this simple format that could make all the difference in an urgent seizure setting."

As previously announced, complete results of the Phase 1b study were shared with the US FDA in an End-of-Phase 1 interaction. The FDA provided feedback that Xeris' drug development program for XP-0863 could advance directly into a Phase 3 registration study in both pediatric and adult patients with epilepsy.

About Diazepam

Diazepam is in a class of medications called benzodiazepines. It works by calming abnormal overactivity in the brain. Diazepam is used in emergency situations to stop cluster seizures (episodes of increased seizure activity) in people who are already taking medications to control their seizures. Diazepam is only recommended for short-term treatment of seizure attacks. Uncontrolled seizures can turn into serious (possibly fatal) seizures that do not stop (status epilepticus).

About Acute Repetitive Seizures

There are over 2.7 million people with epilepsy in the United States with approximately 200,000 new patients diagnosed each year. It is estimated that between 30% and 40% of these patients are uncontrolled on oral therapy and are at risk for acute breakthrough seizures. Acute repetitive or cluster seizures may occur over a number of hours or days and can include any seizure type. Studies have shown that prolonged or repetitive seizures can cause neurological damage and dramatically increase the risk of changes in neuropsychological function or even death.

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 market and therapeutic potential of its product candidates, expectations regarding clinical data or results from planned clinical trials, the timing or likelihood of identifying a potential development and commercialization partner, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, the potential utility of its formulation platforms 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 regulatory approval of its product candidates, its ability to market and sell its products, if approved, its reliance on a single source supplier for Gvoke HypoPen™ , the impact of COVID-19 on its business operations, 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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