Xeris Pharmaceuticals Announces Positive Topline Results From a Study of Its Novel Formulation of Diazepam Injection

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Xeris' IM diazepam maintains higher concentration over longer time period versus standard of care

CHICAGO--(BUSINESS WIRE)--Apr. 20, 2020-- Xeris Pharmaceuticals, Inc. (Nasdaq: XERS), a specialty pharmaceutical company leveraging its novel formulation platforms to develop and commercialize ready-to-use injectable and infusible drug formulations, today announced positive topline results from its Phase 1b weight-based dosing study of diazepam intramuscular (IM) injection utilizing its proprietary XeriSol™ technology.

The Phase 1b, open-label, three-treatment, three-way crossover, randomized controlled study was conducted among 20 healthy volunteers to assess the bioavailability and pharmacokinetics (PK) of two different dose levels of a single, intramuscular (IM), weight-based dose of Xeris' novel formulation of diazepam compared to an administration of commercial diazepam rectal gel (Diastat®). Secondary objectives were to assess the dose proportionality, safety, and tolerability of Xeris' diazepam after IM administration.

In individual comparisons, Xeris' IM diazepam (0.25 mg/kg) administration resembled Diastat® (0.2 mg/kg) for both C_{max} and T_{max}. Xeris' IM diazepam yielded higher drug exposure $AUC_{0-\infty}$ when compared to Diastat®, over 24 hours. Comparing (0.25 mg/kg) to (0.125 mg/kg) IM doses, Xeris' IM diazepam was overall dose proportional. Xeris' IM diazepam was safe and well-tolerated as a single dose with minimal sedation and no safety trends from any treatment group were observed. Adverse events (AEs) included mild to moderate injection site discomfort that was self-limited and fully resolved. No serious adverse events occurred with Xeris' IM diazepam.

"The data show that our 0.25mg dose of IM diazepam maintains a higher concentration of diazepam longer than the proportional dose of Diastat. We believe that the pharmacokinetic properties displayed by our IM diazepam suggest it could be particularly effective in reducing the number of follow-on seizures that so often occur in this patient population," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "Our next step is to bring these data to the FDA to determine the most efficient path forward."

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 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 ove 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 therapeutic potential of its product candidates, the timing of clinical trials and results, 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, the impact of Covid-19 on its business operations and other factors discussed in the "Risk Factors" section of the most recently filed Annual Report on Form 10-K 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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