Xeris Pharmaceuticals Announces Additional Data From a Phase 1b Comparative Study of Its Novel Concentrated Diazepam Formulation (XP-0863) and an Expedited Clinical Path Forward

July 30, 2020

XP-0863 Phase 1b results and regulatory feedback support direct to Phase 3 registration study in both pediatric and adult patients with epilepsy

CHICAGO--(BUSINESS WIRE)--Jul. 30, 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 additional data from the Phase 1b study to evaluate a novel diazepam formulation (XP-0863) in healthy adult subjects. In April 2020, the Company reported positive preliminary topline results from this study. Complete results from this study were presented at the Fifteenth EILAT Conference on New Antiepileptic Drugs and Devices (EILAT XV) on July 27-30, 2020. These data were also presented to the U.S. Food and Drug Administration (FDA) during a recent end-of-Phase 1 interaction.

XP-0863 is a highly concentrated liquid diazepam for intramuscular (IM) injection that is intended for the treatment of seizure emergencies in patients ≥ 2 years of age, with partial onset or generalized convulsive seizures, who are identified jointly by their caregivers and physicians as suffering intermittent and periodic episodes of markedly increased seizure activity. XP-0863 uses the XeriSol™ platform technology to overcome the solubility problems associated with diazepam, reduces injection burden, provides comparable pharmacokinetics to diazepam rectal gel (Diastat®), and may support the prompt and full-dose drug delivery of diazepam during seizure emergencies.

The Phase 1b study was an open-label, weight-based dose, 3-treatment, 3-way crossover study in healthy adult subjects. This study aimed to investigate the pharmacokinetics, safety, and tolerability of two different weight-based doses of intramuscular XP-0863 when compared to a weight-based dose of Diastat rectal gel. Subjects were randomly allocated to a sequence of three treatments: XP-0863 IM (0.25 mg/kg), XP-0863 IM (0.125 mg/kg), or Diastat (0.2 mg/kg). The subjects' diazepam blood levels were monitored over 21 days after drug dosing. XP-0863 showed comparable pharmacokinetics to Diastat, with similar partial AUCs of XP=0863 (0.25 mg/kg) to Diastat early after dosing and with increased overall exposure (AUC0-∞) when compared to Diastat (18800 h*ng/mL versus 10900 h*ng/mL, respectively). XP-0863 (0.25 mg/kg) had comparable Cmax when compared to Diastat (355 ng/mL versus 384 ng/mL, respectively). The weight-based doses of XP-0863 were safe and well tolerated, with minimal sedation and injection site reactions, and no serious adverse events occurred.

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.

"The unique pharmacokinetic profile of XP-0863 may provide clinical advantages for patients ≥ 2 years of age who need diazepam for seizure emergencies. The Phase 1b study results and successful FDA interactions provide both a predictable and expedited development roadmap for XP-0863 as a critical therapy for the epilepsy community," said Paul R. Edick, Xeris' Chairman and CEO . "Our novel diazepam formulation is another important demonstration of the application of our XeriSol technology across multiple therapeutic areas." Mr. Edick continued, "We believe that XP-0863 is valuable asset, and we look forward to finding a suitable development partner in order to initiate a Phase 3 registration study in the future."

For more information, visit www.xerispharma.com.

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 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 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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