Xeris Pharmaceuticals Announces Results From a Phase 1 Study of Its Novel Formulation of Diazepam

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Favorable pharmacokinetic, safety, and tolerability results support continued development of Xeris' diazepam

Phase 2 study to be initiated in 2H2019

CHICAGO, May 01, 2019 (GLOBE NEWSWIRE) -- 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 positive findings from a Phase 1 study of its novel formulation of diazepam.

The Phase 1, open-label, three-treatment, three-way crossover, randomized controlled study was conducted among 24 healthy volunteers to assess the bioavailability and pharmacokinetics (PK) of Xeris' novel formulation of diazepam after intramuscular (IM) and subcutaneous (SC) administration compared to an administration of commercial diazepam rectal gel (Diastat®). Secondary objectives were to assess the safety and tolerability of Xeris' diazepam after SC and IM administration.

Xeris' IM and SC administration of 10 mg diazepam yielded higher exposure as compared to an equivalent dose of diazepam rectal gel as assessed by $AUC_{0-\infty}$. In individual comparisons, Xeris' IM administration resembled diazepam rectal gel (Diastat®) for both C_{max} and T_{max}. Additionally, both Xeris arms were safe and well-tolerated as a single dose. The study found no safety trends in any treatment group.

Based on these results, Xeris anticipates initiating a Phase 2 open-label, single-arm, weight-based dosing study with IM administration of diazepam in patients with seizure disorders in 2H2019.

"These encouraging results confirm that our XeriSol™ technology is capable of producing a concentrated liquid, stable formulation of diazepam for injection with a favorable PK profile as compared to Diastat," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We look forward to advancing this program as we believe there is a need for an easier-to-use administration of diazepam that may be preferred by patients with epilepsy and their caregivers."

Xeris received orphan drug designation in acute repetitive seizures and Dravet syndrome in 2016 and 2018, respectively.

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 is a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use, room-temperature stable injectable and infusible drug formulations. The Company's proprietary XeriSol™ and XeriJect™ formulation technologies are being evaluated for the subcutaneous (SC) and intramuscular (IM) delivery of highly-concentrated, non-aqueous, ready-to-use formulations of peptides, small molecules, proteins, and antibodies using commercially available syringes, auto-injectors, multi-dose pens, and infusion pumps. XeriSol™ and XeriJect™ have the potential to offer distinct advantages over existing formulations of marketed and development-stage products, including eliminating the need for reconstitution, enabling long-term, room-temperature stability, significantly reducing injection volume, and eliminating the requirement for intravenous (IV) infusion. These attributes may lead to products that are easier to use by patients, caregivers, and health practitioners and reduce costs for payers and the healthcare system. Further information about Xeris can be found at www.xerispharma.com.

Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Xeris Pharmaceuticals, Inc., including statements concerning the initiation of a planned Phase 2 clinical trial for diazepam, the market and therapeutic potential of its product candidates, the timing or likelihood of commercialization of its product candidates, 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, 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.

Xeris Investor Contact
Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
awey@xerispharma.com

312-736-1237

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