# Aquestive Therapeutics to Present Crossover Study Data for Libervant™ (diazepam) Buccal Film at 76th Annual Meeting of the American Academy of Neurology

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WARREN, N.J., April 12, 2024 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced a poster presentation highlighting the crossover study for the Company's product candidate, Libervant™ (diazepam) Buccal Film for treatment of children with epilepsy aged two to five, will be presented at the 76th Annual Meeting of the American Academy of Neurology (AAN) in Denver from April 13 to 18, offering both in-person attendance and live online participation in a hybrid format.

"This study underscores our ongoing dedication to enhancing the well-being of individuals battling epilepsy," said Dan Barber, Aquestive President and Chief Executive Officer. "When it comes to the treatment of seizure clusters in pediatric patients with epilepsy between ages two to five, we believe Libervant, as an oral alternative to existing device-based products, will be well-received by this patient population."

**Poster Title:** Crossover Study Evaluating the Effect of Seizures on the Absorption of Diazepam From a Buccal Film Formulation in Children With Epilepsy
**Poster Session 9:** Epilepsy/Clinical Neurophysiology (EEG): Anti-seizure Medications: Mechanisms, Pharmacokinetics, and Urgent Applications
**Presentation Time:** Wednesday, April 17, from 8:00 AM - 9:00 AM.
**Lead Author:** Gary Slatko, MD, Steve Wargacki, PhD, Michael A. Rogawski, MD, PhD

The abstract is available online at American Academy of Neurology Annual Meeting, as well on the Company's website at the following Link.

**About Libervant**
Libervant is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The U.S. Food and Drug Administration (FDA) has granted tentative approval for Libervant for treatment of these epilepsy patients 12 years of age and older, with U.S. market access for Libervant for this age group of patients subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug scheduled to expire in January 2027. The FDA accepted Aquestive's New Drug Application (NDA) for Libervant (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients between two and five years of age in September 2023. Diastat (diazepam) Rectal Gel is the only FDA approved treatment currently available to this pediatric patient population for this indication. Based on the latest information available to the Company, the review of the Libervant NDA for pediatric patients aged two to five remains on track and there are currently no outstanding information requests from the FDA. The NDA for Libervant was assigned a PDUFA target action date of April 28, 2024.

**About Aquestive Therapeutics**
Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by its licensees in the U.S. and around the world and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

**Forward-Looking Statements**
Certain statements in this press release include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the FDA's approval for U.S. market access and related timing of the Libervant NDA for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients between two and five years of age and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027; regarding the potential benefits Libervant could bring to patients; and other statements that are not historical facts.

These forward-looking statements are based on the Company's current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year orphan drug market exclusivity of an FDA approved nasal spray product of another company in effect until January 2027; risk of delays in or the failure to receive FDA approval of the NDA for Libervant for these epilepsy patients between two and five years of age, including the risk that the FDA may require additional clinical studies for approval of Libervant for this age group, and there can be no assurance that the Company will be successful in obtaining any FDA approval for Libervant for U.S. market access; risk that a competing pediatric epilepsy product of Libervant will receive FDA approval prior to the Company's receipt of FDA approval of the Libervant NDA for these epilepsy patients between two and five years of age; risk relating to the unpredictability of the FDA's decisions regarding orphan drug exclusivity; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product should the FDA approve Libervant for U.S. market access; risk in obtaining market access for Libervant for other reasons; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and

implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for our product candidates; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; uncertainties related to general economic, political (including the wars in Ukraine and Israel and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.



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