Aquestive Therapeutics Receives FDA Acceptance of New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film in Pediatric Patients and Assignment of Prescription Drug User Fee Act (PDUFA) Date

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- *FDA Acceptance of Libervant™ (diazepam) Buccal Film NDA for treatment of seizure clusters in patients between two and five years of age*
- *Prescription Drug User Fee Act (PDUFA) target goal date set for April 28, 2024*

WARREN, N.J., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today announced acceptance by the U.S. Food and Drug Administration (FDA) of the Company's NDA for Libervant™ (diazepam) Buccal Film in pediatric patients between two and five years of age and the assignment of a PDUFA goal date of April 28, 2024.

Aquestive's NDA for approval of 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 has been accepted by the FDA. Diastat® (diazepam) Rectal Gel is the only treatment currently available to this patient population for this indication. The Company received tentative approval for Libervant for the treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients 12 years of age and older in August 2022, but Libervant is currently under an orphan drug block to market access until January 2027.

"The FDA's acceptance of our most recent filing for Libervant is another step forward in bringing this important treatment option to patients," said Daniel Barber, Chief Executive Officer of Aquestive. "When it comes to the treatment of seizure clusters in pediatric patients with epilepsy five years of age and under, physicians and caregivers have limited options. We believe Libervant, as an oral alternative to existing device-based products, will be well-received by this patient population, if approved with market access."

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 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 NDA submitted today for Libervant for epilepsy patients between two and five years of age is subject to FDA approval, including for U.S. market access.

About Aquestive
Aquestive is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 Statement
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 approval and related timing of the NDA for Libervant by the FDA 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 with epilepsy between two and five years of age; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged 12 and older, and overcoming the orphan drug market exclusivity of a competing FDA approved nasal spray product extending to January 2027 for this age group of the patient population; regarding the potential benefits Libervant could bring to patients; and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company's

business including with respect to its clinical trials, including site initiation, enrollment and timing and adequacy of clinical trials, on supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals to produce our products.

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 epilepsy patients between two and five years of age or grant U.S. market access for Libervant for any age group of the epilepsy patient population, including as covered under the NDA for Libervant submitted for epilepsy patients aged two to five, by overcoming the seven year orphan drug market exclusivity of an FDA approved competing product in effect until January 2027, and there can be no assurance that the Company will be successful in obtaining any such product approval or approval 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 this pediatric age group of the epilepsy patient population; 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 for any age group of epilepsy patients; risk in obtaining market access for Libervant for other reasons; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of the Company's product development activities; risk of the Company's failure to generate sufficient data in its NDA submission for FDA approval of Libervant, and there can be no assurance that the Company will be successful in obtaining such approval; risk of the rate and degree of market acceptance of our product candidate Libervant; 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 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; 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 development activities for Libervant; uncertainties related to general economic, political, 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 and the Company's other filings with the 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 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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