Aquestive Therapeutics Doses First Patient in Phase 3 Pivotal Clinical Study Evaluating Pharmacokinetics and Pharmacodynamics of Anaphylm™ (epinephrine) Sublingual Film

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- Commences initial Phase 3 study with first orally delivered epinephrine prodrug candidate
- Reaffirms topline data anticipated in first quarter 2024

WARREN, N.J., Dec. 05, 2023 (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 that the first patient has been dosed in its initial Phase 3 pivotal Pharmacokinetic (PK) clinical study of Anaphylm™ (epinephrine) Sublingual Film. Anaphylm is the Company's orally administered epinephrine prodrug product candidate under development for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

The two-part, Phase 3, single-center, open-label, randomized study is designed to compare the PK and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine IM injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The primary objective is to compare the PK of epinephrine following the single administration of Anaphylm to single administration of epinephrine IM injection in healthy adult subjects. The secondary objectives include evaluating PK sustainability following repeat administration and evaluating the safety and tolerability following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors.

"With the dosing of our first patient, we are officially one step closer to reaching our goal of filing our Anaphylm New Drug Application with the FDA in 2024," said Daniel Barber, Chief Executive Officer of Aquestive. "Anaphylm continues to be the first and only non-invasive, orally delivered epinephrine product candidate to demonstrate clinical results comparable to autoinjectors for the emergency treatment of severe allergic reactions, including anaphylaxis. We remain focused on continuing to demonstrate the PK comparability of Anaphylm to existing autoinjectors. We remain excited to address the significant unmet need for an orally delivered, convenient and effective product candidate."

Part A of the two-part Phase 3 is designed as a three-period, three-treatment, six sequence, comparative PK study and is expected to enroll up to 36 subjects. Part A will assess both the PK performance and sustainability of Anaphylm 12mg with the bracketed comparison of an epinephrine autoinjector (EpiPen) and epinephrine manual IM injection. Part B is designed as a four-period, four-treatment, four-sequence, comparative PK study and is expected to enroll up to 64 subjects, inclusive of those who participated in Part A. Part B will assess the PK of a single dose of Anaphylm 12mg with the bracketed comparison of two autoinjectors (EpiPen and Auvi-Q) and the manual IM injection.

About Anaphylm™
Anaphylm is a polymer matrix-based epinephrine prodrug candidate product. The product is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. The tradename for AQST-109 "Anaphylm" has been conditionally approved by the FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About Aquestive Therapeutics
Aquestive is 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 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 advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, regarding the potential benefits Anaphylm

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 regulatory submissions and regulatory reviews and approval of Anaphylm and Libervant, pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

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 associated with the Company's development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm and our other product candidates; risk of the Company's ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's pivotal PK study protocol and other concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm; 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 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 other 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 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 2022 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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