Aquestive Therapeutics to Present Anaphylm™ (epinephrine) Sublingual Film Pharmacokinetic and Pharmacodynamic Data At 2024 Eastern Allergy Conference

May 28, 2024 at 8:00 AM EDT

WARREN, N.J., May 28, 2024 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced that two encore poster presentations highlighting the positive pharmacokinetic (PK) and pharmacodynamic (PD) data from two completed clinical studies for Anaphylm ™ (epinephrine) sublingual film will be presented at the Eastern Allergy Conference (EAC). Taking place from May 30 through June 2, 2024, in Palm Beach, Florida, EAC features the most current information from the field's top experts on Allergy, Asthma and Immunology. Anaphylm is the Company's first and only orally administered epinephrine prodrug product candidate under development for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

"As we continue to highlight the positive results from our Anaphylm clinical trials, we are pleased to present at a conference that brings together so many renowned leaders in the allergy space," said Dan Barber, President and Chief Executive Officer of Aquestive. "Anaphylm has the potential to transform the treatment of severe allergic reactions, including anaphylaxis. Our recently completed Phase 3 pivotal trial met all its expected endpoints and the remaining pre-submission studies are underway as we target filing an Anaphylm New Drug Application with the FDA by the end of 2024."

Poster Title: Epinephrine Administered via Sublingual Film, Manual Injection, or Auto-Injectors in Healthy Adults: Pharmacodynamic Results
Presentation Time: Friday, May 31, 9:45-11am
Lead Author: Gary Slatko, MD

Poster Title: Pharmacokinetics and Pharmacodynamics of Epinephrine Following Administration via Sublingual Film, Autoinjector, or Manual Injection
Presentation Time: Friday, May 31, 9:45-11am
Lead Author: David Golden, MD

These two posters were previously presented at the American Academy of Allergy, Asthma & Immunology Annual meeting and the American College of Allergy, Asthma & Immunology Annual meeting.

The posters are available on the Company's website at the following link.

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 United States Food and Drug Administration (FDA). Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About Aquestive
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 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 the Company's product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including expected clinical trials and clinical study trial dates, the timing of Aquestive's goal of filing a New Drug Application (NDA) for Anaphylm before the end of 2024, the potential benefits Anaphylm 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 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; 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 trial protocol and other concerns identified in the FDA Type C meeting minutes 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; 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 Anaphylm; 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 Anaphylm; and other risks and

uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed 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 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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Investor Inquiries:
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282