Aquestive Therapeutics to Present Anaphylm™ (epinephrine) Sublingual Film Pharmacokinetic and Pharmacodynamic Data at the 2024 AAAAI Annual Meeting

02.15.24 at 8:01 AM EST

- *The clinical trial data show that epinephrine delivered via orally administered Anaphylm™ (epinephrine) Sublingual Film is comparable to epinephrine delivered via autoinjector or manual intramuscular (IM) injection.*
- *Anaphylm candidate, with the potential to be the first and only non-invasive, orally delivered epinephrine product, demonstrates clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of severe allergic reactions, including anaphylaxis.*
- *A Phase 3 pivotal study for Anaphylm is currently underway with topline data anticipated in the first quarter of 2024.*

WARREN, N.J., Feb. 15, 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 positive pharmacokinetic (PK) and pharmacodynamic (PD) data from two completed clinical studies for Anaphylm will be presented at the American Academy of Allergy, Asthma, and Immunology (AAAAI) 2024 annual meeting, which will take place February 23-26 in Washington, D.C. As highlighted in the abstract, Anaphylm PK and PD data were comparable to epinephrine delivered via autoinjector or manual intramuscular injection (IM).

"With discovery and innovation as key themes of this year's meeting, we are eager to present our latest clinical trial data at the upcoming AAAAI Annual Meeting," said Dan Barber, Aquestive President and Chief Executive Officer. "With the potential to be the first and only needle-free orally administered epinephrine, Anaphylm is poised to transform the treatment of severe/life-threatening allergic reactions, if approved by the FDA."

"The data from the Anaphylm studies expands the favorable evidence indicating that epinephrine delivered via sublingual film results in a rapid onset of action with an early, robust increase in pharmacokinetic and pharmacodynamic parameters used to measure epinephrine efficacy," stated David Golden, M.D., Allergist & Immunologist at Medstar Franklin Square Hospital, Baltimore, Maryland. "These results demonstrate that Anaphylm shows promise as a viable needle-free alternative for the treatment of Type I allergic reactions."

Poster Title: Pharmacokinetics and Pharmacodynamics of Epinephrine Following Administration via Sublingual Film, Autoinjector, or Manual Injection
Poster Session: Therapeutic Trials in Allergic Skin Disorders and Anaphylaxis 2024
Poster Number: 034
Presentation Time: Friday, February 23, 3:15-4:15 PM CT
Lead Author: David Golden, MD

The abstract is available online at jacionline.org and annualmeeting.aaaai.org, as well 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. Patient enrollment is underway in the Phase 3 pivotal PK study for Anaphylm for the emergency treatment of severe allergic reactions, including anaphylaxis. In the two-part open-label, randomized study, the pharmacokinetics and pharmacodynamics of single and repeat doses of Anaphylm are being compared to that of epinephrine administered as an intramuscular injection to healthy adult subjects. Aquestive anticipates reporting topline data from the Phase 3 pivotal PK study in the first quarter of 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 advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, the position of Anaphylm as the first and only needle-free orally administered epinephrine product for the treatment of Type I allergic reactions, 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, 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 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 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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