



Aquestive Therapeutics to Present Positive Topline Data from Pharmacokinetic and Pharmacodynamic Studies of Anaphylm™ (epinephrine) Sublingual Film at Aspen Allergy Conference

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WARREN, N.J., July 25, 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 that two posters recapping the positive topline data from pharmacokinetic (PK) and pharmacodynamic (PD) studies of Anaphylm epinephrine sublingual film will be presented at the Aspen Allergy Conference, which will be held from July 30 – August 3 in Aspen, CO.

"Having just presented the data from our PK and PD studies in two encore presentations at the Global Food Allergy Prevention Summit earlier this month, we are thrilled to be given the opportunity to continue to share both presentations at the upcoming Aspen Allergy Conference," said Daniel Barber, Chief Executive Officer of Aquestive. "Anaphylm continues to be a primary focus of our development program as it has the potential to provide a highly differentiated product to patients. Anaphylm is the first oral film candidate in development for the emergency treatment of severe allergic reactions, including anaphylaxis."

Poster Title: Pharmacokinetics and Pharmacodynamics of Epinephrine Sublingual Film Versus Intra-Muscular Epinephrine

Presentation Time: Monday, July 31, 5:00 – 7:00 PM MDT

Lead Author: David Golden, M.D., Medstar Franklin Square Hospital

Poster Title: Impact of Food Exposure on the Pharmacokinetics of Epinephrine Sublingual Film

Presentation Time: Monday, July 31, 5:00 – 7:00 PM MDT

Lead Author: John Oppenheimer, M.D., UMDNJ Rutgers University School of Medicine

About Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction with that is rapid in onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence in the US is at least 5%, or more than 16 million people. Direct costs of anaphylaxis have been estimated at \$1.2 billion per year, with direct expenditures of \$294 million for epinephrine, and indirect costs of \$609 million. The frequency of hospital admissions for anaphylaxis has increased 500–700% in the last 10–15 years. Of patients who previously experienced anaphylaxis, 52% had never received an epinephrine auto-injector prescription, and 60% did not have an auto-injector currently available. The most common causes of anaphylaxis are foods (such as peanuts), venom from insect stings, and medications. Epinephrine injection is the current standard of treatment intended to reverse the severe manifestation of anaphylaxis, which may include skin rash, throat swelling, respiratory difficulty, gastrointestinal distress, and loss of consciousness.

About Anaphylm™

Anaphylm (AQST-109) is a polymer matrix-based epinephrine prodrug candidate product administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. 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 harsh conditions such as exposure to rain and/or sunlight.

About Aquestive Therapeutics

Aquestive Therapeutics, Inc. (NASDAQ: AQST) 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 our licensees in the U.S. and around the world. 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 a developing pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit [Aquestive.com](https://www.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 of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, 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; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and there can be no assurance that we will be successful in obtaining FDA approval 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; risk of the rate and degree of market acceptance of our product candidate Anaphylm; risk of the success of any competing products; 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 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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