Aquestive Therapeutics to Present Positive Data from Pharmacokinetic and Pharmacodynamic Studies for AQST-109 Epinephrine Sublingual Film at American Academy of Allergy, Asthma, and Immunology (AAAAI) Annual Meeting

02.21.23 at 8:00 AM EST

WARREN, N.J., Feb. 21, 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 four late breaking posters recapping the positive data from pharmacokinetic and pharmacodynamic studies of AQST-109 epinephrine sublingual film will be presented at the American Academy of Allergy, Asthma, and Immunology (AAAAI) annual meeting, which will be held from February 24-27 in San Antonio, Texas.

"We are excited to share the positive results from our two completed AQST-109 pharmacokinetic and pharmacodynamic studies at the upcoming AAAAI Conference," said Dan Barber, Aquestive's President and Chief Executive Officer. "We look forward to engaging with leaders in the allergy community and providing insights into how our therapeutic candidate has the potential to provide an important advancement for the treatment of acute allergic reactions, if approved by the FDA."

"Collectively, the AQST-109 studies presented at the 2023 AAAAI add to an accumulating body of favorable evidence indicating that epinephrine delivered via sublingual film results in a rapid onset (i.e., T_{max}) and an early, robust increase in other pharmacokinetic and pharmacodynamic parameters used to measure epinephrine efficacy," stated John Oppenheimer, M.D., FAAAAI, Clinical Professor of Medicine at UMDNJ Rutgers, Pulmonary and Allergy Associated NJ. "The newly presented data also indicate that AQST-109 shows promise as a viable alternative for the management of anaphylaxis."

Poster Title: Impact of Food Exposure on the Pharmacokinetics of Epinephrine Sublingual Film
Poster Number: 7
Presentation Time: Friday, February 24, 3:15-4:15 PM CT
Lead Author: John Oppenheimer, M.D., UMDNJ Rutgers University School of Medicine

Poster Title: Pharmacokinetics and Pharmacodynamics of Epinephrine Sublingual Film Versus Intra-Muscular Epinephrine
Poster Number: 12
Presentation Time: Friday, February 24, 3:15-4:15 PM CT
Lead Author: David Golden, M.D., Medstar Franklin Square Hospital

Poster Title: Pharmacokinetics of Epinephrine Sublingual Film Following Three Different Administration Procedures
Poster Number: 17
Presentation Time: Friday, February 24, 3:15-4:15 PM CT
Lead Author: David Bernstein, M.D., University of Cincinnati College of Medicine

Poster Title: Comparison of the Pharmacokinetic and Pharmacodynamic Profiles of Epinephrine Delivered by a Sublingually Absorbed Film Versus 0.3 mg Administered by a Standard IM Injection or the Epipen®
Poster Number: L13
Presentation Time: Friday, February 24, 3:15-4:15 PM CT
Lead Author: Matthew Greenhawt, M.D., MBA, MSc, Children's Hospital Colorado

The abstracts are available online at jacionline.org and annualmeeting.aaaai.org, as well on the Company's website at the following link.

About Anaphylaxis
Anaphylaxis is a serious systemic hypersensitivity reaction with rapid onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence is at least 5%, or more than 16 million people in the United States. 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. 52% of patients, who previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector 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 problems, gastrointestinal distress, and loss of consciousness.

About AQST-109
AQST-109 is a polymer matrix-based epinephrine prodrug 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 AQST-109 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.

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 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 of our product candidate AQST-109 through clinical development and the potential benefits AQST-109 could bring to patients, if approved by the FDA, 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 AQST-109; 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 the Company's product development activities and clinical trials for AQST-109; risk of the Company's failure to generate sufficient data in its pharmacokinetic (PK) and pharmacodynamics (PD) comparability submission for FDA approval of AQST-109; risk of the Company's failure to address the concerns identified in the FDA End of Phase 2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109, including the risk that the FDA may require additional clinical studies for FDA approval of AQST-109; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); 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; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk of the rate and degree of market acceptance of our licensed and product candidates; the success of any competing products, including generics; 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, business, industry, regulatory 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.

PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Investor Inquiries:
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282



Source: Aquestive Therapeutics, Inc.