Aquestive Therapeutics to Present Positive Data from Pharmacokinetic and Pharmacodynamic Studies of Anaphylm™ (epinephrine) Sublingual Film at the CFAAR Food Allergy Summit

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WARREN, N.J., June 25, 2025 (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 poster presentations highlighting results from the investigational use of Anaphylm™ (epinephrine) Sublingual Film in the treatment of severe allergic reactions, including anaphylaxis, will be presented at the Center for Food Allergy and Asthma Research (CFAAR) Food Allergy Summit , which will be held June 27-29 in Chicago, Ill. The data from these posters was originally presented at the 2025 AAAAI Annual Meeting. If approved by the U.S. Food and Drug Administration (FDA), Anaphylm would be the first and only orally delivered epinephrine option for the treatment of severe allergic reactions in the United States.

Poster presentation details are as follows:

Poster Title: The Physicochemical Properties of Anaphylm Under Extreme Temperatures and Real-World Conditions
Lead Author: Nils Confer, PhD
Presentation Time: Saturday, June 28 from 5:00PM to 7:30PM CST

Poster Title: Epinephrine Delivered via Sublingual Film (Anaphylm) Elicits Rapid and Consistent Pharmacokinetic and Pharmacodynamic Responses
Lead Author: Carl Kraus, MD
Presentation Time: Saturday, June 28 from 5:00PM to 7:30PM CST

The abstracts are available on the Company's website on the Scientific Events page of the Investors section.

About Anaphylm™ (epinephrine) Sublingual Film
Anaphylm™ (epinephrine) Sublingual Film is a polymer matrix-based epinephrine prodrug product candidate. Anaphylm 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 Anaphylm trade name for AQST-109 has been conditionally approved by the U.S. Food and Drug Administration (FDA). Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

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 four 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 candidate for the treatment of severe allergic reactions, including anaphylaxis, and an earlier stage epinephrine prodrug topical gel product candidate for possible various possible dermatological conditions, including alopecia areata. 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, including and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; the advancement of the Company's product candidate AQST-108 through clinical development and approval by the FDA for possible various dermatology conditions including alopecia areata; the potential benefits our products and product candidates could bring to patients; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm and AQST-108; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including with respect to the approval of our filed NDA for Anaphylm, or the failure to receive FDA approval at all for any of our product candidates, including Anaphylm and AQST-108; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's clinical trials and other concerns identified in the FDA's Type C meeting minutes and filing review letter for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk that the FDA may require that an Advisory Committee be required for the approval of Anaphylm and that the Company is able to address any concerns raised by such Advisory Committee or the FDA after review of the advice from the Advisory Committee; risk of the success of any competing products, including generics; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund commercialization activities relating to fund future clinical development and commercial activities for our product candidates, including Anaphylm, should these product candidates be approved by the FDA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. of Anaphylm and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the size and growth of our product markets; risk 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 our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office (USPTO); risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions; risks related to uncertainties about U.S. government initiatives and their impact on our business, including imposition of tariffs and other trade restrictions; and other unusual items; and other uncertainties affecting us including those 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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