Aquestive Therapeutics Announces that FDA Will Not Require an Advisory Committee Meeting to Discuss New Drug Application for Anaphylm™

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- *NDA remains on track for FDA PDUFA goal date of January 31, 2026*
- *Commercial planning continues enabling rapid launch following approval*

WARREN, N.J., Sept. 04, 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 the U.S. Food and Drug Administration (FDA) has informed the Company that an advisory committee meeting is not required for Anaphylm™ (dibutepinephrine) Sublingual Film. The Prescription Drug User Fee Act (PDUFA) target action date for Anaphylm remains January 31, 2026.

Anaphylm has the potential to be the first and only FDA-approved, non-invasive, orally delivered epinephrine product for the treatment of severe allergic reactions, including anaphylaxis. If approved, people at risk for severe allergic reactions would have a device-free, needle-free epinephrine option. Similar in size to a postage stamp, Anaphylm is administered as a thin, dissolvable film placed under the tongue.

"We are encouraged that the FDA has determined that an advisory committee meeting is not required for approval of Anaphylm," said Dan Barber, President and CEO of Aquestive Therapeutics. "Our device-free, sublingual epinephrine film, is designed to offer patients and caregivers an alternative to traditional auto-injectors and other emerging non-invasive options. If approved by the FDA, we believe Anaphylm would mark a meaningful advancement in anaphylaxis treatment. We are well-positioned for launch and, based on our recent $160 million in financing activities, we will have the ability to ensure broad outreach to healthcare providers, caregivers, and patients following FDA approval."

Anaphylaxis is a severe, rapid allergic reaction requiring immediate application of epinephrine, but many patients hesitate to use epinephrine injections due to fear of needles. Aquestive Therapeutics' Anaphylm is the first sublingual epinephrine film, offering a device-free, patient-friendly alternative. Eleven clinical studies have been completed, with 967 administrations in total (840 single-dose and 127 repeat-dose) for adults and children over 30 kg. The development program also includes a novel trial for oral allergy syndrome demonstrating Anaphylm's real-world effectiveness.

About Anaphylm™ (dibutepinephrine) Sublingual Film
Anaphylm™ (dibutepinephrine) 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 the 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 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 dermatology conditions. 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™ (dibutepinephrine) Sublingual Film through clinical development and approval by the FDA, including 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; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care treatment, if Anaphylm is approved by the FDA; the advancement of the Company's product candidate AQST-108 through clinical development and regulatory approval by the FDA for

possible various dermatology conditions; 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 (including for pediatric patients) and AQST-108; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the NDA for AQST-108, or the failure to receive FDA approval at all of 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 and questions regarding the Company's clinical trials and the NDA for Anaphylm and other concerns of the FDA 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 associated with the success of any competing products, including generics; risk associated with the development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Anaphylm; 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 commence principal payments under our 13.5% Notes in 2026, to fund future clinical development and commercial activities for our product candidates, including Anaphylm, should these product candidates be approved by the FDA; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates, if approved by the FDA, and our licensed products in the U.S. and abroad; 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; risks associated with failure to comply 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 United States Patent and Trademark Office; 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 product 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 and other unusual items; risks related to the uncertainty about presidential administration initiatives and their impact on our business, including the imposition of tariffs and other trade restrictions; 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 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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