Aquestive Therapeutics Announces Completion of Type A Meeting with FDA for Anaphylm™ (dibutepinephrine) Sublingual Film

03.30.26 at 7:00 AM EDT

- *Reaffirms guidance to resubmit the Anaphylm NDA in Q3 2026*
- *Received clarifying feedback from the FDA on pharmacokinetic (PK) and human factor (HF) study designs*
- *Final FDA meeting minutes expected by early May 2026*

WARREN, N.J., March 30, 2026 (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 the receipt of preliminary comments and successful completion of an in-person Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the resubmission of the Company's New Drug Application (NDA) for Anaphylm™ (dibutepinephrine) sublingual film for the treatment of Type 1 allergic reactions, including anaphylaxis.

“The Type A Meeting with FDA confirmed our approach on several key program elements, and we are grateful to the Agency for the productive dialogue on the next steps for our Anaphylm program,” said Daniel Barber, President and Chief Executive Officer of Aquestive. “We are already hard at work preparing for our human factors and PK studies in support of our planned Anaphylm NDA resubmission in the third quarter of this year. We continue to believe Anaphylm, the first and only oral epinephrine rescue medication, has the potential to be transformative for those at risk of life-threatening allergic reactions. We want to thank the many patients, healthcare providers, and patient advocacy organizations who have expressed support for our program. Our commitment to address the long-unmet needs of this community remains strong.”

Aquestive provided the proposed PK study design to the FDA prior to the Type A meeting and received preliminary comments in advance of the meeting. Most of the preliminary comments provided by the FDA were focused on ensuring consistency between past PK studies conducted by the Company and the proposed current design. The Company plans to address all feedback received by the Agency in the PK study design. In addition, the Company and FDA aligned on the concept of including labeling language to manage potential chewing of the film rather than creating additional clinical data.

The FDA also provided preliminary comments on Aquestive’s HF validation study design provided by the Company to the FDA prior to the meeting. The FDA recommended changes to the user groups to be included in the HF study design and, after discussion at the Type A meeting, the Company believes there is general alignment with the FDA on key HF study elements. Aquestive plans to submit the HF study protocol for FDA review, as recommended by the FDA. During the meeting, the Company shared with the FDA the revisions made to the opening mechanisms of the product container closure, which were designed to provide improvements in the ability to open the pouch while also mitigating the potential tearing of the film. The FDA acknowledged the changes made to the Anaphylm container closure, which will be tested in the Company’s upcoming HF study.

Based on the outcome of the Type A meeting, Aquestive reaffirms its guidance to resubmit the Anaphylm NDA in the third quarter of 2026. The Company also continues to advance regulatory submissions for Anaphylm in Canada and the European Union. 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.

About Anaphylm™ (dibutepinephrine) Sublingual Film
Anaphylm™ (dibutepinephrine) sublingual film is a polymer matrix-based epinephrine prodrug investigational drug product. 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 primary 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 FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About Aquestive Therapeutics, Inc.
Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. The worldwide leader in delivering trusted, quality medications on oral film, Aquestive operates as both a developer of its own proprietary products and a Contract Development and Manufacturing Organization (CDMO) for licensees, with its headquarters in New Jersey and U.S.-based manufacturing facilities in Indiana. The Company is the exclusive manufacturer of four commercialized products marketed by its licensees across six continents using proprietary, best-in-class technologies like PharmFilm®. Aquestive's AdrenaVerse™ platform contains a library of more than 20 epinephrine prodrugs enabling the pursuit of various potential allergy and dermatological indications. The Company is advancing Anaphylm™ (dibutepinephrine) sublingual film for the treatment of severe allergic reactions, including anaphylaxis, and AQST-108 (epinephrine prodrug) topical gel for various potential dermatological conditions, including alopecia areata. For more information,

visit Aquestive.com and follow us on LinkedIn.

Forward Looking Statement

This press release contains certain 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™ (dibutepinephrine) sublingual film through clinical development and regulatory approval by the FDA for the treatment of Type 1 allergic reactions, including anaphylaxis, and the related timing of development activities and regulatory approval, including the resubmission of the Anaphylm NDA in the third quarter of 2026; that the Company and FDA are aligned on the proposed elements of the study designs and protocols for the planed Anaphylm studies to be included in the resubmitted Anaphylm NDA; the ability of the Company to address the concerns raised by the FDA in the preliminary comments on the materials and information provided by the Company to the FDA prior to the Type A meeting and feedback from the FDA during the Type A meeting, including that the revisions to the product packaging will address the concerns raised by the FDA regarding the product container closure design; the timing of receipt of the final minutes of the Type A meeting from the FDA; the advancement and related timing of potential international regulatory filings and marketing authorization of Anaphylm outside of the U.S.; that Anaphylm will be the first and only oral administration of epinephrine, if Anaphylm is approved by the FDA; the potential benefits Anaphylm could bring to patients, if approved by the FDA, and acceptance as an alternative to existing standards of care for the treatment of Type 1 allergic reactions, including anaphylaxis; the advancement of the Company’s AdrenaVerse™ epinephrine prodrug product pipeline, including AQST-108 (epinephrine) topical gel, through clinical development and FDA regulatory approval process for potential treatment indications, including alopecia areata for AQST-108; and business strategies, market opportunities, and other statements that are not historical facts.

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 our development work, including any delays or changes to the timing, cost and success of the Company’s product development activities and clinical trials and plans for Anaphylm and the Aquestive's AdrenaVerse™ platform, including for AQST-108, for the pursuit of various potential allergy and dermatological indications; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates Anaphylm (including delays in the resubmission of the Anaphylm NDA and FDA’s issuance of final minutes to the Type A meeting and review of the Anaphylm NDA) and AQST-108, or failure to receive FDA approval at all of either of these product candidates; risk of FDA inspections of manufacturing and clinical study sites for any of our product candidates, including Anaphylm and AQST-108; risk of government shutdowns or actions to reduce government workforces on the ability of the FDA to act on the approval of our product candidates, including Anaphylm and AQST-108; risk of the Company’s ability to generate sufficient clinical and other human factor data, including with respect to our submission of pharmacokinetic and pharmacodynamic (PK/PD) comparability data and revisions to Anaphylm’s product packaging, for FDA approval of Anaphylm; risks associated with our ability to address the FDA’s comments on and identified deficiencies in the Anaphylm NDA, including the concerns raised by the FDA in the Complete Response Letter, dated January 30, 2026, and whether the FDA may request further information from the Company (including additional clinical and human factor studies), disagree with our study designs and protocols, findings or otherwise undertake a lengthy review of the resubmission of our NDA; risk that Anaphylm will not be the first and only oral administration of epinephrine, if a competing product is approved prior to an approval of Anaphylm by the FDA; risk of challenges regarding the following commercial launch of Anaphylm, if approved by the FDA; 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 for Anaphylm outside of the U.S., including delays in the submission of the Company’s market authorization applications for the advancement of the regulatory approval process through regulatory authorities outside of the U.S.; risk of delays in advancement of the regulatory approval process of Anaphylm by foreign regulatory authorities, or failure to receive approval at all of Anaphylm; risks associated with 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 development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm and AQST-108, if these product candidates are approved by the FDA; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product candidates, including Anaphylm and AQST-108; 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 to support our growth strategy, and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm and AQST-108, should these product candidates be approved by the FDA; risk of the impact of our obligations under the Company's Purchase Agreement and the Royalty Rights Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Senior Secured Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, including Anaphylm, if approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunsetting product, which accounts for a 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. and abroad of our product candidates, including Anaphylm, if approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets and expected related revenues and sales; risk associated with our 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 or, if issued, will be sufficient to provide long-term commercial success of these product candidates; 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 us 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 changing interest rates; risks related to the impact of pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine, Iran and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of government tariffs and other trade restrictions; 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, 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.

Investor Contact:
Brian Korb
astr partners
brian.korb@astrpartners.com