Aquestive Therapeutics Announces Resubmission of New Drug Application to FDA for Anaphylm™ (dibutepinephrine) Sublingual Film

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- Resubmission supported by positive topline human factors and pharmacokinetic (PK) study results announced in August 2026
- FDA will determine the resubmission classification and establish the applicable review timeline following its initial review of the resubmission

WARREN, N.J., Sept. 17, 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 that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Anaphylm™ (dibutepinephrine) sublingual film for the treatment of Type I allergic reactions, including anaphylaxis.

"This resubmission reflects the rigor of our response to the FDA's Complete Response Letter, and we believe it addresses the items identified by the FDA in the Complete Response Letter," said Daniel Barber, President and Chief Executive Officer of Aquestive Therapeutics. "The completed studies generated human factors, pharmacokinetic, and pharmacodynamic data supporting the revised packaging design and instructions for use, including reducing median pouch-opening time from 17 seconds to 3 seconds. Our conviction in Anaphylm's potential has never been stronger. As we prepare for a focused, allergist-first launch, if approved, we are moving with urgency to bring Anaphylm to the patients who need it most."

"When a patient experiences an anaphylactic reaction, rapid access to and administration of epinephrine are critically important," said David B.K. Golden, M.D.C.M., lead author of the 2023 Anaphylaxis Practice Parameter and a member of Aquestive's Scientific Advisory Board. "A small, highly portable and needle-free treatment option has the potential to address important barriers associated with carrying and administering epinephrine. Importantly, Anaphylm has previously demonstrated a rapid onset together with robust increases in heart rate and blood pressure; these pharmacodynamic responses were comparable to or greater than those observed with auto-injectors and manual IM epinephrine in clinical studies. Taken together, these characteristics suggest that Anaphylm, if approved, could represent a meaningful advancement in the treatment of severe allergic reactions, including anaphylaxis."

The Company's original NDA for Anaphylm was submitted in March 2025. The FDA issued a Complete Response Letter (CRL) on January 30, 2026, which requested that the Company complete a human factors study addressing packaging and administration, and a confirmatory pharmacokinetic (PK) study of Anaphylm. Following receipt of the CRL, Aquestive held a Type A meeting with the FDA to discuss the Company's proposed approach to addressing the matters identified in the CRL.

In response to the CRL, Aquestive completed a human factors study evaluating revised packaging that incorporated modifications to the pouch opening, instructions for use, and pouch and carton labeling. The Company also completed a confirmatory PK study in healthy volunteers using the revised packaging and revised instructions for use, which evaluated self-administration and clinician administration of Anaphylm and included manual intramuscular epinephrine as a comparator. No protocol-defined use errors were observed in the self-administration arm of the PK study.

About Anaphylm™ (dibutepinephrine) Sublingual Film

Anaphylm™ (dibutepinephrine) sublingual film is a polymer matrix-based epinephrine prodrug investigational 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

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 Type I allergic reactions, including anaphylaxis, and AQST-108 (epinephrine) topical gel for various potential dermatological 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 Anaphylm™ (dibutepinephrine) sublingual film through the FDA regulatory review and approval process; our ability to address the matters identified by the FDA in the Complete Response Letter ("CRL") dated January 30, 2026; the FDA's review, classification and timing of our NDA resubmission for Anaphylm; the establishment and timing of any FDA review goal date; the significance, interpretation and sufficiency of the human factors and pharmacokinetic study results and the pharmacokinetic and pharmacodynamic data supporting the NDA resubmission; whether the NDA resubmission adequately addresses the deficiencies identified by the FDA in the CRL; the potential approval of Anaphylm by the FDA; the Company's commercial launch strategy for Anaphylm, if approved; and other statements that are not historical facts. Such forward-looking statements also include statements regarding anticipated timelines, milestones and guidance relating to regulatory submissions, clinical studies, regulatory interactions, and potential approvals, which are inherently uncertain and subject to change based on regulatory feedback, data sufficiency and other factors outside the Company's control.

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, the risk that the FDA may determine that the NDA resubmission does not constitute a complete response to the CRL; the risk that the FDA may classify the resubmission differently than the Company anticipates, resulting in a longer review period than expected; the risk that the FDA may not establish a review goal date within the timeframe anticipated by the Company; risks that preliminary, topline, interim or summary human factors, pharmacokinetic or pharmacodynamic results may differ from final analyses or may be interpreted differently by regulatory authorities; the possibility that the FDA may disagree with the Company's interpretation of study results, findings or conclusions, or may request additional information, analyses, human factors studies or clinical studies; risks associated with our ability to address the FDA's comments on and identified deficiencies in our NDA, including the concerns raised by the FDA in the CRL, and whether the FDA may request further information from us (including additional studies), disagree with our protocols, study designs or findings, or otherwise undertake a lengthy review of our NDA resubmission; the risk that the FDA may consider issues raised in one or more citizen petitions or similar submissions relating to Anaphylm; risks associated with our development activities, including delays or changes to the timing, cost or success of our product development programs and clinical studies for Anaphylm; risks of delays in, or failure to obtain, regulatory approval of Anaphylm; risks related to government shutdowns, reductions in government workforce or other governmental resource constraints that may adversely affect the FDA's ability to review or act upon regulatory submissions in a timely manner or at all; and other uncertainties affecting the Company described in the "Risk Factors" section and elsewhere 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 undertakes no obligation to update any forward-looking statement after the date of this press release, whether as a result of new information, future events or otherwise, except as required by applicable law.

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