# Aquestive Therapeutics Provides International Expansion Update for Anaphylm™ (epinephrine) Sublingual Film

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- *New Drug Submission meeting scheduled with Health Canada for the third quarter of 2025*
- *Initial briefing book submitted for review to the European Medicines Agency*

WARREN, N.J., July 15, 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, announced today that Health Canada has granted the Company a meeting to discuss Aquestive's planned New Drug Submission (NDS) for Anaphylm™ (epinephrine) Sublingual Film in Canada. In addition, the Company has submitted an initial briefing book to the European Medicines Agency (EMA). The Company plans to submit a Marketing Authorization Application (MAA) to the EMA as soon as possible.

"These regulatory activities mark the pivotal first steps in Aquestive's comprehensive ex-U.S. regulatory strategy," said Dan Barber, President and Chief Executive Officer of Aquestive. "With our U.S. FDA New Drug Application recently accepted and a PDUFA target action date of January 31, 2026 established, we're now positioned to pursue parallel regulatory pathways with the potential to bring needle-free, device-free Anaphylm to patients underserved by current treatment options. Our proven ability to successfully bring innovative therapies to market globally, combined with our oral epinephrine approach, positions us to fundamentally change how patients and caregivers manage severe allergic reactions, including anaphylaxis."

Aquestive brings significant regulatory and commercialization experience to this expansion effort, with six FDA-approved drugs in its portfolio and products currently available across six continents. This established global footprint and regulatory track record positions the Company to efficiently navigate international approval processes.

Unlike traditional epinephrine auto-injectors that require needles, Anaphylm™ is administered orally, addressing critical barriers to treatment, including needle phobia, device malfunction concerns, and portability challenges that affect patient compliance and emergency response.

The Company's ex-U.S. regulatory strategy prioritizes markets with significant unmet medical needs and regulatory frameworks conducive to innovative therapies. EMA and Canada represent ideal initial international markets given their collaborative regulatory environment and substantial population of patients requiring reliable anaphylaxis treatment options.

Aquestive will continue to provide updates on its global regulatory approval progress as it works to establish Anaphylm as the new standard of care for the treatment of severe allergic reactions and anaphylaxis worldwide.

**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 dermatology 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, Health Canada and EMA; the expected plans for regulatory approval and commercialization of Anaphylm in markets outside of the United States, if approved by the applicable regulatory authorities, including in Canada and the European Union; 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 delays in advancement of the regulatory approval process outside the U.S. of our product candidates, including Anaphylm in Canada and the European Union; 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 and AQST-108, should these product candidates be approved by the FDA, Health Canada and EMA; 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 and outside of the U.S. of Anaphylm and our other product candidates, should these product candidates be approved by the FDA, Health Canada and EMA, 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.



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