Aquestive Therapeutics Spotlights its Innovative Epinephrine Delivery Pipeline at Virtual Investor Day

September 27, 2024 at 8:30 AM EDT

- Announces completion of enrollment in its oral allergen challenge study for the development of its late-stage pipeline program, Anaphylm™ (epinephrine) Sublingual Film
- Outlines the development strategy for the Company's next pipeline product candidate, AQST-108 (epinephrine) Topical Gel for the treatment of Alopecia areata
- Holds virtual investor day

WARREN, N.J., Sept. 27, 2024 (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 hosted a virtual investor day highlighting the Company's pipeline inclusive of Anaphylm™ (epinephrine) Sublingual Film and AQST-108 (epinephrine) Topical Gel, both product candidates emerging from the Company's Adrenaverse™ epinephrine prodrug platform. The event included presentations by members of the Aquestive management team and by distinguished key opinion leader J. David Farrar, PhD, Associate Professor, Immunology/Molecular Biology, UT Southwestern Medical Center.

"Our pipeline is progressing, and we are excited about the next chapter for growth. We recently submitted our pre-NDA meeting request to the FDA for Anaphylm and are on track to report topline data from our oral allergy challenge study in the coming weeks," remarked Daniel Barber, President and Chief Executive Officer of Aquestive. "This is an exciting time for the Company and for our stakeholders, most importantly the patients we seek to help. As our next step for the Adrenaverse platform, we will focus on developing AQST-108 for the treatment Alopecia areata, based on our candidate's differentiated therapeutic profile and significant unmet need in this indication."

"Epinephrine plays a critical role in immune suppression but, until now, its role has been limited due to issues in the absorption and conversion of epinephrine," said Carl Kraus, MD, Chief Medical Officer of Aquestive. "Our Adrenaverse platform has demonstrated the ability to harness the therapeutic potential of epinephrine through highly differentiated prodrug formulations, which can achieve absorption, provide sustained local exposure and avoid systemic exposure. The platform makes it possible to deliver epinephrine locally across mucosal surfaces and the skin and, therefore, we believe that it has the potential to yield multiple product candidates focused on treating a range of diseases. AQST-108 for the treatment of Alopecia areata is a natural next step in the evolution of this platform."

Anaphylm™ (epinephrine) Sublingual Film
Aquestive outlined today that it has completed enrollment in its remaining supportive study for Anaphylm, the oral allergy syndrome (OAS) challenge study, which is expected to be completed in the fourth quarter of 2024 following the completion of dosing. The Company remains on track to hold the pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2024 as it has recently submitted a meeting request letter to the FDA. Aquestive remains focused on completing an NDA submission with the FDA in the first quarter of 2025 and initiating a full product launch of Anaphylm, if approved by the FDA, at the end of 2025 or in the first quarter of 2026.

AQST-108 (epinephrine) Topical Gel
The Company completed its first human clinical study for AQST-108. The two-part study was designed to assess the safety and local tolerability of AQST-108. Part 1 was designed as a single ascending dose escalation study to assess the safety and pharmacokinetics of five different dose levels. The 1.0% dose of AQST-108 was chosen based on the highest dose found with no appreciable transdermal absorption in order to move into the Part 2 study of the development program. In Part 2, three formulations based on excipient variations were evaluated in twelve healthy subjects. In Parts 1 and 2, no serious adverse events or topical adverse events were observed. In Part 2, the calculated percentage of AQST-108 observed in the skin remained consistent across all studied formulations and zero post dose AQST-108 concentrations in plasma were observed.

Aquestive unveiled in the event its plan to develop AQST-108 for the treatment of Alopecia areata, which impacts as many as 6.7 million people in United States. AQST-108, a topically delivered adrenergic agonist prodrug, has the potential to support immune privilege in the hair follicle. The Company outlined the design of its planned Phase 2 study to assess the safety and efficacy of AQST-108 in mild to moderate Alopecia areata patients. The Company expects to hold a pre-Investigational New Drug (IND) meeting with the FDA in the first quarter of 2025 and to commence the Phase 2 study in the second half of 2025, pending alignment with the FDA.

The Investor Day webcast and accompanying written presentation (including discussion on the planned clinical and regulatory pathway and potential commercial opportunity) may be accessed through the Events & Presentations page in the Investors section of the Company's website at https://investors.aquestive.com/events-and-presentations. The webcast will be archived for 30 days.

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 FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About AQST-108 (epinephrine) Topical Gel

AQST-108 (epinephrine) Topical Gel is a topically delivered adrenergic agonist prodrug gel product candidate. Aquestive completed a first in human study for AQST-108 that measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel and without any serious or topical adverse events. AQST-108 is based on Aquestive's Adrenaverse™ platform that contains a library of over twenty epinephrine prodrug product candidates intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

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 five 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 for 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, including the timing of submission of supporting and pediatric clinical studies, holding a pre-NDA meeting with the FDA and filing the NDA for Anaphylm with the FDA, 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, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel (and potential alternative indications), through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of Alopecia areata for AQST-108, and holding a pre-IND meeting with the FDA, and the following launch of AQST-108, if approved by the FDA; the potential indications and 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), AQST-108, and the Company's other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm and AQST-108, or the failure to receive FDA approval at all of any of these product candidates; 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 Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; 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 the Lincoln Park Purchase Agreement, 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; 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 AQST-108 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 success of any competing products including generics; 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 and AQST-108, will not be timely issued, or issued at all, by the PTO; 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, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; 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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