Aquestive Therapeutics Announces Successful Completion of Phase 1 Trial for AQST-108 (Sublingual Film Formulation Delivering Systemic Epinephrine)

September 30, 2019

- Represents Significant Proof-of-Concept Milestone for Sublingual Epinephrine Pipeline Product -

WARREN, N.J., Sept. 30, 2019 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products to solve therapeutic problems, today announced the successful completion of its Phase 1 dose escalation proof-of-concept study in healthy subjects for AQST-108. AQST-108 is a “first of its kind” oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive’s proprietary PharmFilm ® technologies.

Importantly, the data demonstrated that AQST-108:

- achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables EpiPen® and Auvi-Q®
- provided a greater total exposure ($AUC_{0-t;}$ area under the curve) than that reported for EpiPen and Auvi-Q
- had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q
- was well tolerated, with no study participants discontinuing participation due to an adverse event

Based on the results of this proof-of-concept study, Aquestive is in the process of scheduling a pre-IND meeting with the U.S. FDA.

“We’re very pleased with the proof-of-concept data that demonstrated our ability to deliver systemic epinephrine via our PharmFilm formulation,” said Keith J. Kendall, Chief Executive Officer of Aquestive. “Anaphylaxis is a serious condition that impacts a large patient population. The only options currently available to patients require an injection. We believe we have the technology that can bring meaningful innovation and positive change for patients. We plan on meeting with the U.S. FDA as soon as possible to discuss the further development of AQST-108 and we are focused on providing the first highly portable, easy-to-administer and anxiety-free oral sublingual film medication to treat this serious condition.”

Anaphylaxis is a potentially life-threatening systemic allergic reaction, with an estimated incidence of 50 to 112 episodes per 100,000 people per year. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years.[1] The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. Epinephrine injection is the current standard of treatment intended to reverse the potentially severe manifestation of anaphylaxis, which may include red rash, throat swelling, respiratory problems, gastrointestinal distress and loss of consciousness.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Forward-Looking Statement
This press release includes 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 may include, but are not limited to, statements regarding the therapeutic benefit and safety profile of AQST-108, the applicability of interim results to the results of later trials, the development and commercialization of AQST-108, plans and objectives for present and future clinical trials for AQST-108 and results of such trials, plans and objectives for regulatory approval; statements about our growth and future financial and operating results and financial position, ability to advance Libervant and our other product candidates to the market, regulatory approvals and pathways, clinical trial timing and plans, short-term and long-term liquidity and cash requirements, cash funding and cash burn, 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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in FDA approval of our drug candidates or failure to receive approval; risk inherent in

commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk that a competitor obtains orphan drug exclusivity and blocks our product for the same indication for seven years; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; 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 of our products and product candidates; 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 the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; risk of claims and concerns that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. Given these 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 us or any person acting on our 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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[1] Epidemiology of anaphylaxis. Tejedor Alonso MA, Moro Moro M, Mugica Garcia MC, Clin Exp Allergy. 45(6):1027-39, Jun 2015

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