Aquestive Therapeutics Announces Positive EPIPHAST II Trial Data for AQST-109 When Compared to EpiPen®

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- *AQST-109 median time to maximum concentration (Tmax) of 12 minutes was faster than EpiPen® Tmax of 22.5 minutes*
- *AQST-109 repeat dosing provided significantly higher drug plasma concentrations with a Tmax of 8 minutes after administration*
- *Changes in systolic blood pressure and heart rate were similar after a single dose of AQST-109 when compared to a single dose of EpiPen*
- *End-of-Phase 2 meeting with FDA scheduled for fourth quarter 2022 and remaining clinical studies will commence thereafter*
- *Company hosts conference call at 8:00 am ET on September 27, 2022*

WARREN, N.J., Sept. 27, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today announced positive topline results from the EPIPHAST II trial for its AQST-109 epinephrine sublingual film.

"Speed matters in delivering systemic epinephrine during an anaphylaxis event. Any delay can result in severe bronchospasm, acute respiratory failure and/or cardiovascular collapse, as well as less favorable outcomes and death," said David Bernstein, MD, University of Cincinnati. "AQST-109 continues to demonstrate fast delivery of therapeutic levels which are necessary to stop anaphylaxis at an early stage and prevent progression to a more severe reaction."

The EPIPHAST II trial was designed to compare single doses of AQST-109 to EpiPen® 0.3mg and epinephrine 0.3mg intramuscular (IM) injection, as well as repeat doses of AQST-109 to repeat doses of epinephrine 0.3mg IM injection. Results from the single dose administration showed AQST-109 achieved a significantly faster Tmax (12 minutes), compared to both EpiPen® (22.5 minutes) and epinephrine 0.3mg IM injection (45 minutes). AQST-109 repeat dosing provided significantly higher drug plasma concentrations, with a Tmax of 8 minutes after administration, and extensive absorption was observed. The mean maximum concentration (Cmax) of AQST-109 was 465 pg/mL after one dose and 2,958 pg/mL after two doses. In comparison, the epi 0.3mg IM injection Cmax was 489 pg/mL after one dose and 911 pg/mL after two doses. The single dose of EpiPen resulted in a Cmax of 869 pg/mL.

After one dose of AQST-109, maximum mean effects on systolic blood pressure occurred within 5 minutes of dosing compared to 8 minutes for EpiPen. Maximum mean effects in heart rate occurred within 8 minutes of administering AQST-109 compared to an average of 5 minutes within administering EpiPen. Safety results for AQST-109 were in line with expectations, and no severe or serious adverse events were reported.

"We are pleased to see that AQST-109 compared favorably to both the EpiPen and the epi 0.3mg IM injection across several measures," said Daniel Barber, Chief Executive Officer of Aquestive. "This is a meaningful step forward for this program and brings us closer to improving the lives of people who are looking for alternatives to the current standard of care for allergic reactions. Literature suggests that over 40 million Americans are at risk for acute anaphylactic episodes. Yet, over half of those who have experienced anaphylaxis have never received an epinephrine auto-injector prescription. We believe AQST-109 will provide a meaningful addition to treating anaphylaxis and we look forward to sharing the full dataset with the FDA, which will be the basis for our end-of-Phase 2 meeting scheduled for the fourth quarter of 2022."

Today's Conference Call and Webcast
Management will host a conference call for investors at 8:00 a.m. ET on Tuesday, September 27, 2022. In order to participate, please register here in advance to obtain a local or toll-free phone number and your personal pin.

The live webcast will be available on 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 Anaphylaxis
Anaphylaxis is a serious systemic hypersensitivity reaction with rapid onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence is at least 5%, or more than 16 million people in the United States. Direct costs of anaphylaxis have been estimated at $1.2 billion per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. 52% of patients, who previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector currently available. The most common causes of anaphylaxis are foods (such as peanuts), venom from insect stings, and medications. Epinephrine injection is the current standard of treatment intended to reverse the severe manifestation of anaphylaxis, which may include skin rash, throat swelling, respiratory problems, gastrointestinal distress, and loss of consciousness.

About AQST-109
AQST-109 is a polymer matrix-based epinephrine prodrug administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. The product 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 AQST-109 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.

About Aquestive Therapeutics
Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products in the U.S. and around the world. 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 pipeline focused on treating diseases of the central nervous system, or CNS, and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. 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 AQST-109 through the regulatory and development pipeline and clinical and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 for AQST-109 and our other product candidates; risk of delays in FDA approval of AQST-109, Libervant™ (diazepam) Buccal Film and our other drug candidates or failure to receive FDA approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; 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 liquidity and cash requirements and other cash needs, at the times and in the amounts needed; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks 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 actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks 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 and associated costs, including patent infringement, investigative and antitrust litigation matters; changes in government 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 uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities 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 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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