Aquestive Therapeutics Presented Positive Topline Phase 1 Results for AQST-109 Epinephrine Oral Film at American Academy of Allergy, Asthma, and Immunology (AAAAI) Annual Meeting

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WARREN, N.J., Feb. 28, 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, presented a late breaking poster recapping positive topline data from a Phase 1 pharmacokinetic study of AQST-109 epinephrine oral film at the American Academy of Allergy, Asthma, and Immunology (AAAAI) annual meeting, which was held from February 25-28 in Phoenix, Arizona.

Poster Title: A Phase 1, Randomized Study Evaluating the Safety Tolerability, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Single Ascending Doses of Epinephrine Prodrug 109 Sublingual Film (AQST-109) in Healthy Male Volunteers
Poster Number: L37
Presentation Time: February 28, 2022, at 9:45 am MST

Lead Author: John Oppenheimer, M.D., FAAAAI, Clinical Professor of Medicine at UMDNJ Rutgers, Pulmonary and Allergy Associates NJ

"This poster presentation provides the opportunity to share our first-in-human data for AQST-109 to the international allergy community," stated John Oppenheimer, M.D., FAAAAI, Clinical Professor of Medicine at UMDNJ Rutgers, Pulmonary and Allergy Associates NJ. "Dosing with AQST-109 resulted in PK and PD responses that were within the expected therapeutic range. This is the first time it has been demonstrated that epinephrine can achieve therapeutic blood concentrations following sublingual administration. AQST-109 shows promise as a viable alternative to injection for the management of anaphylaxis. I look forward to further evaluation of this investigational medicine."

The webcast of Dr. Oppenheimer's presentation is available for viewing to registered attendees in the AAAAI Meeting Library.

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. The Investigational New Drug Application (IND) was opened by the FDA on February 24, 2022. Separately, Health Canada provided clearance to continue our adaptive design crossover study. The Company expects to move forward with the manufacture of registration batches and to conduct pivotal studies for AQST-109 in 2022.

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. The Company has four approved and licensed products and commercialized one internally-developed proprietary product to date, Sympazan® (clobazam) oral film. The Company also has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to 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
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 AQST-109 through the regulatory and development pipeline 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 U.S. Food and Drug Administration (FDA) approval of AQST-109, Libervant™ (diazepam) Buccal Film, and our other drug candidates or failure to receive 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 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; short-term and long-term liquidity and cash requirements, cash funding and cash burn; 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 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 matters challenging third party at risk generic sale of our proprietary products, and other 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 (SEC). 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.

Investor Inquiries
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282

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