Aquestive Therapeutics Receives Conditional FDA Acceptance of Proprietary Name Anaphylm™ for Lead Candidate AQST-109 (Epinephrine Sublingual Film)

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WARREN, N.J., April 20, 2023 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today announced the U.S. Food and Drug Administration (FDA) has conditionally accepted the proprietary name Anaphylm™ as the proposed brand name for AQST-109, the Company's polymer matrix-based epinephrine prodrug administered as a sublingual film in development for the treatment of severe allergic reactions including anaphylaxis.

The proprietary name Anaphylm (pronounced "ana-PHYLM") was developed after an extensive process involving external branding experts as well as patient feedback. The "ANA" portion of the name is derived from "anaphylaxis" and the "PHYLM" portion of the name is designed to remind patients and caregivers of the oral film product form. The Company also completed a research study of healthcare practitioners across the U.S. to promote accurate prescription and safety interpretation of the name. Anaphylm was developed in accordance with FDA's guidance for the submission and evaluation of proprietary names. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate, AQST-109.

"We are pleased that the FDA has conditionally accepted the name Anaphylm for AQST-109," said Daniel Barber, Chief Executive Officer of Aquestive. "This is yet another important step towards making Anaphylm available to patients. According to literature, almost half of patients said that they didn't have their autoinjector with them during a severe allergic reaction and even when available, it is often not used due to reasons such as needle phobia. We believe changing this paradigm starts with improving how patients and caregivers interact with their prescribed product. The conditional branding of AQST-109 as Anaphylm is just one of the steps we are taking to lower the barriers to patient use."

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. The reported incidence of anaphylaxis in the United States is 49.8 in 100,000 person-years, with a prevalence of approximately 1.6% to 5.1%. 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 Anaphylm ™
Anaphylm (AQST-109) is a polymer matrix-based epinephrine prodrug candidate product 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 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.

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 marketed by our licensees 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 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 Statements
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 potential benefits Anaphylm could bring to patients, that the brand name of Anaphylm will promote accurate prescription and safety interpretation by healthcare prescribers, 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 the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company's 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 its product development activities and clinical trials for Anaphylm; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm; risk of insufficient capital and cash resources, including insufficient access to available

debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the 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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