Aquestive Therapeutics Enters License and Supply Agreement with Pharmanovia for Libervant™ (diazepam) Buccal Film for European and MENA Markets

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WARREN, N.J., Sept. 28, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("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 it has entered a license, and supply agreement for Libervant™ (diazepam) Buccal Film with Pharmanovia, a global lifecycle management healthcare company, for treatment of prolonged or acute, convulsive seizures in all ages, across the European Union, United Kingdom, Switzerland, and Norway, as well as countries in the Middle East and North Africa (MENA).

"We are very excited to enter into this agreement with Pharmanovia, which will extend Libervant's reach to patients across the world, if approved by the applicable regulatory authorities," said Daniel Barber, Chief Executive Officer of Aquestive. "Libervant has the distinct advantage of being able to be readily administered when needed without regard to food, which is important to patients as rapid and extensive drug absorption is critical in a rescue situation. As we continue to engage with the FDA for Libervant market access in the US, we are thrilled to join forces with a company that shares our vision. This agreement is also a great example of levers we have for non-dilutive financing options for our business as we continue to focus on progressing our AQST-109 epinephrine sublingual film pipeline product, and as we are continuing to evaluate and engage in discussions regarding opportunities to out-license or sell our products and other assets."

Pharmanovia CEO, James Burt, commented, "Pharmanovia and Aquestive are aligned in our mission to find new and innovative ways to enhance and revitalize iconic medicines. We have extensive experience with diazepam through the Valium® brand and, together with Aquestive's unique PharmFilm® technology, we are intending to bring a novel alternative diazepam delivery option to caregivers and patients at a time of critical need."

Pursuant to the agreement, Aquestive Therapeutics will serve as the exclusive sole manufacturer and supplier for the product and Pharmanovia will be responsible for all regulatory and commercialization activities. Aquestive will receive an undisclosed upfront payment and, if approved, milestone payments, and double-digit royalties on net sales of the diazepam buccal film in the licensed territories.

About Libervant
Libervant™ is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The U.S. Food & Drug Administration (FDA) has granted tentative approval for Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Approximately 1.0 million patients with epilepsy suffer from uncontrolled refractory seizures, approximately 85% of whom will not interact with the available treatments.

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.

About Pharmanovia
Pharmanovia is a global lifecycle management healthcare company. Its mission is to revitalize iconic medicines for the benefit of patients, prescribers, and payors, and utilize our capabilities to launch novel therapies. With a diverse and growing team in over 140 countries across the globe, we deliver high-quality solutions, ethically and sustainably, across our four core therapeutic areas – Oncology, Endocrinology, Neurology and Cardiovascular.

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 regulatory approval and commercialization of Libervant outside of the United States, advancement 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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Investor Inquiries
ICR Westwicke
Stephanie Carrington
Stephanie.carrington@westwicke.com
646-277-1282

Source: Aquestive Therapeutics, Inc.