Aquestive Therapeutics Expands License and Supply Agreement with Pharmanovia for Libervant™ (diazepam) Buccal Film to Additional Global Markets

03.29.23 at 8:30 AM EDT

WARREN, N.J., March 29, 2023 (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 it has expanded its exclusive license and supply agreement with Atnahs Pharma UK Limited ("Pharmanovia"), a global pharmaceutical company that revitalizes, extends and expands the lifecycle of established medicines, for Libervant™ (diazepam) Buccal Film to cover the rest of the world, excludingthe United States, Canada, and China. The original licensing agreement with Pharmanovia announced in September 2022 covered the European Union, United Kingdom, Sweden, Switzerland, and Norway, as well as countries in the Middle East and North Africa (MENA).

"We are pleased to announce the expansion of our collaboration with Pharmanovia," said Daniel Barber, Chief Executive Officer of Aquestive. "We believe Pharmanovia's experience and geographic footprint align well with our goal of providing patients throughout the world with access to Libervant. This announcement also aligns with our mission to put the patient at the center of everything we do. We will continue to advocate for patient access, patient choice, and patient empowerment on a global basis."

Pharmanovia CEO, James Burt, commented, "Following a strong start to our collaboration with Aquestive Therapeutics, we've expanded our agreement to include many more territories. Our experience with diazepam marketed under an established brand in Valium®, combined with Aquestive Therapeutics' unique PharmFilm ® technology, provides a potentially significant delivery option to caregivers and patients in times of critical need and enables us to optimize an existing medicine to better meet the needs of patients, healthcare professionals and payors."

Pursuant to the expanded 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 for market access, 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, with U.S. market access for Libervant subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug scheduled to expire in January 2027. 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 marketed by its licensees in the U.S. and around the world, and is the exclusive manufacturer of these licensed products. 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.

About Pharmanovia
Pharmanovia is a global lifecycle management healthcare company. Our 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 160 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 approval of Libervant by the FDA for U.S. market access and overcoming orphan drug market exclusivity of a competing FDA approved product extending to January 2027; statements regarding the potential approval of Libervant by regulatory authorities in the licensed territories; statements regarding the potential benefits Libervant could bring to patients; 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 AQST-109; 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 the Company's product development activities and clinical trials for our product candidate AQST-109 for the treatment of severe allergies, including anaphylaxis, and our other product candidates;; risk of delays in or the failure to receive FDA approval of AQST-109, including the risk that the FDA may require additional clinical studies for FDA approval of AQST-109, and there can be no assurance that the Company will be successful in obtaining such approval; risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year orphan drug market exclusivity of an FDA approved competing product in effect until January 2027, and there can be no assurance that the Company will be successful in obtaining such approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of our ability to out-license our proprietary products or enter into other commercial transactions with third parties; 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; 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 that we are unable to refinance our current corporate debt on terms and conditions satisfactory to the Company, or not at all; risk of eroding market share for Suboxone® and risk of a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of the rate and degree of market acceptance of our licensed 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; uncertainties related to general economic, political, business, industry, regulatory and market conditions, including inflation and rising interest rate risks, 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.

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

Source: Aquestive Therapeutics, Inc.