Aquestive Therapeutics Completes Rolling Submission of New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for Libervant™ (diazepam) Buccal Film for Management of Seizure Clusters

December 2, 2019

WARREN, N.J., Dec. 02, 2019 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ:AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products that meet patients' unmet needs and solve therapeutic problems, today announced the completion, as planned, of the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its therapeutic candidate Libervant™ (diazepam) Buccal Film for the management of seizure clusters. Libervant has received orphan drug designation from the FDA.

"We are very pleased to have completed our NDA filing for Libervant as we had committed. We look forward to sharing the results from the single dose crossover study at the upcoming American Epilepsy Society 2019 Annual Meeting. We believe these results confirm our dosing algorithm and satisfy the final clinical requirement requested by the FDA," remarked Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "We believe that Libervant has the potential to be the first oral therapy approved by the FDA for the management of seizure clusters in the population of 1.2 million refractory epilepsy patients and the first diazepam based treatment usable by and delivering a consistent predictable dose to virtually all patients to whom it will be prescribed."

About Libervant
Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. Aquestive is developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with refractory epilepsy, which as a rectal gel, is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. It is anticipated that Libervant will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and 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.

PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. Aquestive has received conditional acceptance of the use of the trade name Libervant, which is subject to final FDA review and acceptance.

Forward-Looking Statement
This press release includes 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 may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approval of Libervant and other product candidates; statements about our growth and future financial and operating results and financial position, ability to advance Libervant and our other product candidates to the market, regulatory approvals and pathways, clinical trial timing and plans, short-term and long-term liquidity and cash requirements, cash funding and cash burn, business strategies, market opportunities, and other statements that are not historical facts.

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; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk that a competitor obtains orphan drug exclusivity and blocks our product for the same indication for seven years; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; 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; 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 associated with Indivior's announcement of its intention to cease production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk 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 action 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, including patent infringement, investigative and antitrust litigation matters; changes in governmental

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 risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. Given these 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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