Aquestive Therapeutics Completes Enrollment in Libervant™ (diazepam buccal film) Crossover Study

June 4, 2019

- Files first section of rolling New Drug Application (NDA) submission with U.S. Food and Drug Administration (FDA)

- Crossover study completes enrollment and is progressing ahead of schedule

WARREN, N.J., June 4, 2019 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company, today announced it has completed enrollment in a single dose crossover pharmacokinetic (PK) trial for Libervant ™ (diazepam buccal film), which is in development for the management of select patients with refractory epilepsy who require treatment to control episodes of increased seizure activity, or "seizure clusters." The Company also initiated a rolling New Drug Application (NDA) submission for Libervant in May 2019 with the U.S. Food and Drug Administration (FDA).

The single dose crossover study is designed to compare Libervant and its reference listed drug, Diastat® Rectal Gel, in the same patient population, and provide the final set of data validating the Libervant dosing model. Aquestive has exceeded its target enrollment in the study and dosed more than 24 adult patients. Based on the approved study protocol, each patient is intended to receive a single dose each of Libervant and Diastat. The administration of each medication is being randomized over two visits, with a minimum 28-day wash-out period required between the first and second dosing. The primary endpoints are measures of blood plasma levels - including Cmax, Tmax, and AUC measurements - monitored for 10 days following each dosing. Additionally, the study will track product safety and tolerability. Analysis of this data will be done in the third quarter 2019 and be used to complete the NDA filing in the fourth quarter 2019.

"We are pleased that the crossover study recruitment and expected date of study completion are both tracking ahead of schedule, and we are moving ahead with the NDA filing," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics.

Among the 3.4 million epilepsy patients in the U.S., an estimated 1.2 million experience refractory or breakthrough seizures. These patients require a rescue strategy they can employ at the onset of increased seizure activity to prevent high cost emergency situations and poor outcomes. The current standard for treatment is Diastat, a rectal gel formulation of diazepam, which is underused by the patient population. Limited alternatives have left most patients without an effective and preferred treatment option.

"Libervant can provide the right medicine, at the right dose, in a form many patients would prefer to use," continued Mr. Kendall. "We believe Libervant will be an important innovation that can provide a material contribution to, and improvement in patient care, increasing the options and solutions available for patients, prescribers and caregivers seeking a reliable and fast-acting rescue treatment for breakthrough seizures or seizure clusters."

Libervant is a novel formulation of diazepam administered as a thin film strip, placed inside the cheek. Libervant leverages Aquestive's proprietary PharmFilm® technology. If approved, Libervant can be carried by patients and administered without invasiveness to help lessen subsequent 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.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "project," "will," "would," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. Such statements include, but are not limited to, statements about regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, product orders and fulfillment, future financial and operating results, business strategies, market opportunities, financing, 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; the risks of delays in FDA approval of our drug candidates or failure to receive approval; the risks inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); development of our sales and marketing capabilities; issues related to the outsourcing of certain operational and staff functions to third parties; the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; the size and growth of our product markets; the effectiveness and safety of our products and product candidates; risks associated with intellectual property rights

and infringement, including the outcome of any patent infringement litigation relating to the Company's products; 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 concerns that may arise regarding the safety or efficacy of the Company's products and product candidates; risks related to legal proceedings, including ongoing patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; the impact 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 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019, as updated in our subsequent quarterly report 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 guidance in SEC filings after the date of this press release whether as a result of new information, future events or otherwise, except as may be required under applicable law.

Media inquiries:
Christopher Hippolyte
christopher.hippolyte@syneoshealth.com
212-364-0458

Investor inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282

View original content to download multimedia:http://www.prnewswire.com/news-releases/aquestive-therapeutics-completes-enrollment-in-libervant-diazepam-buccal-film-crossover-study-300861209.html

SOURCE Aquestive Therapeutics, Inc.