Aquestive Therapeutics Announces Positive Topline Results from Libervant™ (Diazepam) Buccal Film Single Dose Crossover Study

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- The study confirms the dosing algorithm developed for Libervant (diazepam) buccal film, a potentially first in class oral treatment for breakthrough or cluster seizures
- Libervant adult rolling New Drug Application (NDA) submission expected to be completed in the fourth quarter of 2019

WARREN, N.J., Aug. 06, 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 topline results from the recently completed single dose crossover study 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 single dose crossover study was designed to compare diazepam maximal plasma [or blood] concentrations from a dose of Libervant and its reference drug, a diazepam rectal gel, in the same patient population, and provide the final set of data to confirm the proposed dosing regimen for Libervant. Subjects were dosed in accordance with body weight into one of four weight categories. A total of 28 of the 31 patients enrolled were included in the primary analysis. Patients eligible for analysis were stable on concurrent anti-epileptic medications (no changes to concomitant medications allowed from 30 days prior to dosing and throughout the study). Subjects were dosed within 30 minutes of the start of a moderate fat meal and monitored for 10 days after each dose.

Topline results show the study met its co-primary endpoints for diazepam maximal plasma concentration (C_{max}), Area Under the Curve (AUC), and time to maximal concentration (T_{max}). As quality reviews and statistical analyses continue, the preliminary findings include:

- Diazepam exposure following the buccal film showed comparable bioavailability to the rectal gel as assessed by maximal plasma concentration (C_{max}). Across the four weight classes, buccal film demonstrated more consistent C_{max} values than was observed in this study for rectal gel.
- The bioavailability of diazepam administered as the buccal film, assessed by AUC, was comparable or higher than rectal gel for the study population overall and also within each of the four weight categories. This finding suggests that any effect of enzyme induction from concomitant medications acted with equal effect on the film and the gel.
- The T_{max} of diazepam film administration in patients under fed conditions was comparable to the results from previous studies of healthy volunteers who were under fasting conditions.

Three patients failed to achieve therapeutic concentrations of diazepam when using rectal gel. There were no such failures following buccal film administration.

"We believe Libervant can be a major contribution to patient care for refractory epilepsy patients seeking a better alternative to existing therapies for the management of breakthrough seizures," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "We believe the results of this study confirm our dosing algorithm and satisfy the final clinical requirement requested by the FDA. We expect to successfully complete the NDA filing this year and bring Libervant to patients in 2020, following approval."

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 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 about our growth and future financial and operating results and financial position, ability to advance Libervant 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; 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); 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 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 the effectiveness and safety of our products and product candidates; 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 concerns 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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