Aquestive Therapeutics Announces Late-Breaking Findings of its Investigational Diazepam Buccal Film (DBF) Formulation in Adults with Epilepsy

December 3, 2018

-- Studies show DBF, tentatively named Libervant™, was successfully administered and had similar bioavailability whether given during/immediately following a seizure or between seizures

-- DBF, utilizing Aquestive's PharmFilm® technology, is in development as the first oral alternative to injected or rectally administered diazepam for acute treatment of seizures

WARREN, N.J., Dec. 3, 2018 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company, today announced findings from two clinical studies, including the Adult Epilepsy Monitoring Unit (EMU) study, showing that its investigational diazepam buccal film (DBF) was successfully used and had similar bioavailability whether administered between seizures (interictal) or during or shortly after seizures (ictal/peri-ictal) in adults with poorly controlled tonic-clonic seizures or focal seizures with impaired awareness. The findings are detailed in two presentations at the 72nd annual meeting of the American Epilepsy Society.

Investigational diazepam buccal film (DBF), tentatively named Libervant ™, is a novel formulation of diazepam as a small, thin film strip for placement inside the cheek. Libervant leverages Aquestive's proprietary PharmFilm® technology, and is in development for the management of selected patients with refractory epilepsy who require intermittent use of diazepam to control episodes of increased seizure activity.

"Currently, the only formulations of diazepam approved by the U.S. Food and Drug Administration (FDA) for acute treatment of seizures are injected or rectally administered, which can be cumbersome and uncomfortable for patients who suffer from repetitive seizures," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "These findings, showing consistent usability and bioavailability, demonstrate Libervant's potential to address patient needs for an orally administered treatment alternative that is efficacious, easy to use and portable anywhere. We are excited to add this to our growing epilepsy franchise."

Findings from the diazepam buccal film (DBF) EMU study

The separate presentations on DBF bioavailability and usability were based on a Phase 2, multicenter, open-label, crossover study in 35 adult men and women (ages 17-65 years) with poorly controlled tonic-clonic seizures or focal seizures with impaired awareness, who were being evaluated in an epilepsy monitoring unit or EMU. The participants received two treatments of DBF 12.5 mg separated by approximately three weeks: Treatment A, during interictal conditions, and Treatment B during ictal/peri-ictal conditions (during or within 5 minutes of a seizure). A total of 33 participants received Treatment A, and 33 participants received Treatment B.

The analysis demonstrating similar bioavailability during interictal and ictal/peri-ictal administration was based on pharmacokinetic data from 21 participants with valid pharmacokinetic data who received both Treatment A and Treatment B: specifically, diazepam maximal plasma concentration (C_{max}), time to maximal concentration (T_{max}), and partial area under the diazepam plasma concentration curve (partial AUC) at 2 or 4 hours following DBF administration. The ratio of geometric means for partial AUC at 2 hours comparing Treatment B (ictal/peri-ictal conditions) to Treatment A (interictal conditions) was 94% with a 90% confidence interval of 74% - 119% while the ratio of geometric means for C_{max} was 93% with a 90% confidence interval of 75% - 113%. Mean C_{max} levels for a dose of 12.5 mg DBF were 199 ng/mL and 184 ng/mL for Treatments A and B respectively. Median T_{max} values were less than one hour for both conditions.

The most common adverse event possibly related to DBF was somnolence (sleepiness or drowsiness) reported in two (5.7%) of the 35 participants. There were no serious adverse events related to DBF, and no participant withdrew because of an adverse event.

The study also examined DBF's usability, based on correct administration of the film. This data is important in showing that an oral alternative can be accurately administered to patients. The study found that in all cases DBF was successfully placed and generally used without difficulty in both interictal and ictal/periictal states.

Abstracts with details of the study and results are available online at www.aesnet.org.

About Aquestive Therapeutics

Aquestive Therapeutics is a specialty pharmaceutical company committed to identifying, developing and commercializing differentiated products to

address unmet medical needs. Aquestive Therapeutics has a late-stage proprietary product pipeline focused on the treatment of CNS diseases, and is working to advance orally-administered complex molecules that it believes can be alternatives to invasively-administered standard of care therapies. As the leader in developing and delivering drugs via its PharmFilm® technology, Aquestive Therapeutics also collaborates with pharmaceutical partners to bring new molecules to market in differentiated and highly-marketable dosage forms.

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," "expects," "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, 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; the rate and degree of market acceptance of our product candidates; the success of any competing products; the size and growth of our product markets; the effectiveness and safety of our product candidates; risks associated with intellectual property rights and infringement; unexpected patent developments; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Registration Statement on Form S-1 declared effective by the SEC on July 24, 2018. As with any pharmaceutical product candidate under development, there are significant risks with respect to the development, regulatory approval and commercialization of new products. 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. We assume no obligation to update our forward-looking statements 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.

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