



Aquestive Therapeutics Announces Completion of Diazepam Buccal Film Adult Epilepsy Monitoring Unit (EMU) Clinical Study with Positive Topline Results

October 25, 2018

WARREN, N.J., Oct. 25, 2018 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company, today announced the completion of a pharmacokinetic epilepsy monitoring unit (EMU) study demonstrating that its investigational diazepam buccal film (DBF), tentatively named Libervant™, provides comparable bioavailability whether administered between seizures (interictal) or during and shortly after seizures (ictal/peri-ictal) in adult patients with poorly controlled tonic-clonic seizures or focal seizures with impaired awareness. DBF, a novel formulation of diazepam as a small, thin film strip placed inside the cheek, is under development for the management of selected patients with refractory epilepsy who require intermittent use of diazepam to control episodes of increased seizure activity.



"Often it can be very difficult to administer treatment during periods of increased seizure activity. Currently, the only non-injected formulation of diazepam approved for the acute treatment of seizures is a rectally-applied gel," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "These pharmacokinetic findings, taken together with other DBF studies, will help advance the development of Libervant as an alternative to currently approved therapies. We are very excited to have achieved this critical milestone in the program."

In this single-dose cross-over study, investigators determined 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 administration of 12.5 mg of DBF to the patients while they underwent a clinical epilepsy monitoring unit evaluation. Results from this study have been accepted for late-breaking presentation at the upcoming 2018 meeting of the American Epilepsy Society.

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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