Aquestive Therapeutics Announces U.S. Food and Drug Administration (FDA) Acceptance of New Drug Application for Riluzole Oral Film for Treatment of ALS

April 16, 2019

WARREN, N.J., April 16, 2019 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products to solve therapeutic problems, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for the investigational product riluzole oral film (ROF), which the Company intends to market under the brand name Exservan ™. ROF is a novel formulation of riluzole, which is used as an adjunctive therapy in the treatment of amyotrophic lateral sclerosis (ALS). The PDUFA (Prescription Drug User Fee Act) goal date is November 30, 2019. The Company is exploring commercial opportunities for ROF in the U.S. and abroad.

"We're pleased the FDA has accepted our NDA for Exservan, given the needs ALS patients have for treatment advances. ALS, though relatively rare, represents a considerable economic and social burden in the U.S. and globally," said Daniel Barber, Chief Strategy and Development Officer of Aquestive. "Oral films offer great promise to patients who face difficulty swallowing or administering traditional forms of medication. In addition to Exservan, we are also focused on advancing Libervant toward an NDA filing this year. We believe these innovations are important and can help patients interact consistently and compliantly with their medication."

The development of ROF with PharmFilm® technology included studies demonstrating the product's pharmacokinetic bioequivalence to the reference listed drug, Rilutek®, as well as additional studies to assess patients' ability to swallow ROF. Aquestive believes that ROF can fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

Riluzole oral film received FDA orphan drug designation in January 2018.

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 pharmaceutical partners 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," "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; 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 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. 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 our forward-looking statements or 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.

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