Aquestive Therapeutics Provides Update on Licensee, Sunovion Pharmaceuticals Inc.'s Apomorphine Sublingual Film (APL-130277) New Drug Application

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WARREN, N.J., Jan. 31, 2019 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products to solve therapeutic problems, learned today its licensee, Sunovion Pharmaceuticals Inc., received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to the New Drug Application (NDA) for apomorphine sublingual film (APL-130277). APL-130277 is a medicine to treat OFF episodes (the re-emergence or worsening of Parkinson's symptoms otherwise controlled by medications) experienced by people living with Parkinson's disease (PD).

"Additional treatment options for PD patients experiencing OFF episodes are important to the PD community. We believe interest in apomorphine film is high," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics."While APL-130277 is not an Aquestive pipeline program, it remains indicative of the future value in our intellectual property (IP) license with Sunovion. We will continue to proactively engage in opportunities to monetize all of our passive assets."

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 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 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, including the outcome of patent infringement litigation relating to the Company's products (including the ongoing ANDA lawsuits); 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 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 Quarterly Report on Form 10Q for the period ended September 30, 2018, filed with the Securities and Exchange Commission (SEC) on November 6, 2018, and the risk factors discussed in our prospectus dated July 24, 2018, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933. 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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