Aquestive Therapeutics Announces Tentative FDA Approval for Sympazan™ (clobazam) Oral Film

August 31, 2018

- Sympazan is an oral soluble film formulation of clobazam, a benzodiazepine indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older

- Sympazan will be delivered via Aquestive's proprietary PharmFilm® technology

WARREN, N.J., Aug. 31, 2018 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) today announced that Sympazan ™(clobazam) oral film has received tentative approval by the U.S. Food and Drug Administration (FDA), for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older. Currently, clobazam is marketed as ONFI® and offered in two formulations - either tablet or oral suspension.

"We saw a need in the LGS community for a simpler, more consistent way to administer a full dose of clobazam - and we are now one step closer to bringing this important treatment to patients, caregivers and physicians," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "This tentative approval for Sympazan is a key milestone for Aquestive, as it represents the first in a series of late stage proprietary products Aquestive plans to commercialize once they are approved. We believe Sympazan and our other products in development solve important therapeutic problems, and will meaningfully improve the lives of patients and their caregivers."

Lennox-Gastaut Syndrome is a severe form of epilepsy that begins in early childhood and is characterized by multiple types of seizures and intellectual disability. LGS patients often have difficulty swallowing pills and large volume suspensions due to physical limitations, behavioral or compliance issues. Challenges with treatment administration can lead to uncertain and inconsistent dosing, and increase the burden of care, particularly for patients that may be combative or resistant to treatment.

Sympazan is a proprietary formulation based on Aquestive's proven PharmFilm® technology. Multiple pharmacokinetic studies were conducted to compare Sympazan with ONFI. Based on the studies, Sympazan oral film was demonstrated to be bioequivalent to clobazam tablets and have comparable safety.

Final FDA approval for Sympazan is pending the expiration of the orphan drug exclusivity period for ONFI, which is expected in October 2018.

About Aquestive Therapeutics

Aquestive Therapeutics is a specialty pharmaceutical company focused on 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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