Aquestive Therapeutics Provides Business Update

January 7, 2021

- **Resubmitted revised dosing regimen for Libervant to FDA in December 2020, as committed**
- **Multiple clinical trials demonstrate that AQST-108 can consistently deliver epinephrine**

WARREN, N.J., Jan. 07, 2021 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, today provided an update on recent developments in its business.

"Given the progress on Libervant™ and AQST-108, 2021 will be an exciting and important year in the continued growth of Aquestive and for the execution of our corporate, clinical and commercial strategy," said Keith J. Kendall, President and Chief Executive Officer of Aquestive. "As we look ahead to 2021, our focus will be on the advancement of Libervant and epinephrine through our regulatory and development pipeline, as well as growing our commercial sales of Sympazan® and continuing to manufacture Suboxone® and other licensed products from our film manufacturing capabilities."

Key Highlights:

Libervant. As previously announced, at a Type A meeting held on November 12, 2020, the U.S. Food and Drug Administration (FDA) confirmed that the issues identified in the Complete Response Letter (CRL) related to the New Drug Application (NDA) for the Company's drug candidate Libervant™ (diazepam) Buccal Film for management of seizure clusters may be addressed by utilizing modeling and simulations based upon the information provided by Aquestive in its FDA meeting package submitted in October 2020. Key updates are:

- The Company resubmitted a revised weight-based dosing regimen along with modeling and simulations in December 2020.
- Based on correspondence from the FDA, the Company expects to receive feedback and guidance from the FDA in late January.
- The Company expects to resubmit the NDA, based on further FDA feedback, during the first half of 2021.

Epinephrine. Utilizing Aquestive's PharmFilm® technologies, AQST-108 is a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. Key updates are:

- Aquestive completed its second Phase 1 pharmacokinetic (PK) trial in 24 healthy adult subjects, which featured a 4-treatment crossover design comparing pharmacokinetics, safety and pharmacodynamics of epinephrine administered in a sublingual film to that of epinephrine administered via both subcutaneous and intramuscular injections.
- The data from multiple trials demonstrate that AQST-108 can consistently deliver epinephrine sublingually and all subjects had measurable plasma concentrations of epinephrine.
- Based on top-line study results, AQST-108 was generally well-tolerated, with adverse events observed that are consistent with the known adverse events profile for epinephrine.
- AQST-108 achieved a similar time to maximal concentrations, or median Tmax, when compared to both the subcutaneous and intramuscular injections of epinephrine.
- The Company plans on commencing another PK trial in the first quarter of 2021 as it continues to progress towards a final product formulation and dose.

"The topline data from the second PK study for AQST-108 provides further evidence that we have developed a unique technological solution that can deliver epinephrine through oral administration," said Mr. Kendall. "The study provides valuable insight into how our technology works. In 2021, we will continue to advance our program by conducting additional human studies as well as working closely with the FDA. We look forward to providing more insight on our technological solution at an R&D day to be scheduled in the first quarter of 2021. Regarding our drug candidate, Libervant, we look forward to receiving feedback from the Agency and resubmitting our NDA as quickly as possible."

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies 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 Statements
Certain statements in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the

advancement of Libervant and AQST-108 through the regulatory and development pipeline; the focus on growing the Company's commercial sales of Sympazan® and continuing to manufacture Suboxone® and other licensed products; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; clinical trial timing and plans for AQST-108; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 and plans for AQST-108 and our other drug candidates; risk of delays in FDA approval of Libervant and AQST-108 and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of our drug candidate Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI monetization, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable, and for funding the Company's operations; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; our and our competitors' orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk associated with Indivior's cessation of production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those 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 forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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