



Aquestive Therapeutics Appoints Mark Lepore, MD, as Chief Medical Officer for Allergy

January 28, 2021

- **New hire helps lead Aquestive's continued focus on its epinephrine program**
- **Provides update on Libervant™ (diazepam) Buccal Film**

WARREN, N.J., Jan. 28, 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 announced the appointment of Mark Lepore, MD, as the Chief Medical Officer for Allergy.

Dr. Lepore is a board-certified allergist and pediatrician. He has over fourteen years of drug development experience, including serving as Vice President, Head of Clinical Strategy and Development for Inhalation and Complex Injectable Products, and Vice President, Global Clinical Development, at Lupin Pharmaceuticals, Inc., and previous clinical research roles in respiratory therapeutics at Teva Pharmaceuticals. Prior to joining industry, Dr. Lepore spent over a decade in private practice as an allergy and asthma specialist and served as a clinical investigator in over one hundred industry-sponsored trials. He received his medical training at Thomas Jefferson University.

"I am very pleased to welcome Mark to the team," said Dan Barber, Chief Operating Officer of Aquestive. "His background in allergy combined with his product development experience are a great match for our programs focused within the allergy space. This is an exciting time for Aquestive and, as we continue to advance our pipeline in 2021, our epinephrine delivery platform will be a key area of focus. Patients at risk for anaphylaxis continue to have very limited treatment options except for injectables. We believe that our platform has the potential to change this dynamic and thereby reduce patients' unmet needs. I look forward to working with Mark as we continue to advance and expand our product development pipeline. Mark will be an important part of our planned R&D event highlighting our epinephrine program during the third week of March."

"Investing in talented and experienced product development experts is an important building block for the company in 2021," said Keith Kendall, President and Chief Executive Officer of Aquestive. "At the same time, we remain fully committed and focused on the resubmission of our Libervant™ (diazepam) Buccal Film application. We continue to interact with the FDA on Libervant and they have indicated that we will receive their feedback in writing in the coming weeks. We continue to believe that we will be able to resubmit our NDA for Libervant shortly after receiving the FDA's written feedback."

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® (clobazam) oral film, 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 other product candidates through the regulatory and development pipeline; the focus on growing the Company's commercial sales of Sympazan®; ability to 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 our drug candidate Libervant and AQST-108 and our other drug candidates or failure to receive approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of 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 transaction, 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 sunseting 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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