



Aquestive Therapeutics Negotiates Six Month Extension to June 30, 2022 for Additional Libervant™ Related Capital Under Current Debt Agreement

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- Provides access to \$30 million in capital contingent on FDA approval and U.S. market access for Libervant

WARREN, N.J., Aug. 09, 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, announced today that it has reached an agreement with its lenders to amend the base indenture providing an extension of the term by six months to June 30, 2022 to provide additional debt in the aggregate of up to \$30.0 million. In line with the extension to June 30, 2022, Aquestive is entitled, at its option, to draw up to \$10 million following FDA approval for Libervant, the first orally delivered diazepam product for the management of seizure clusters, and up to an additional \$20 million following the FDA grant of U.S. market access for Libervant.

"We continue to believe that our non-invasive and innovative product for refractory epilepsy represents a meaningful improvement in the treatment options available to this patient population and a significant commercial opportunity. We appreciate the continued support from our lenders and their flexibility given the current PDUFA date for Libervant. With this six month extension, we maintain the capital optionality and may access to up to \$30 million under our existing debt facility that we can potentially utilize to fund the launch of Libervant, if approved for market access," said Keith Kendall, Chief Executive Officer of Aquestive.

The FDA has accepted for filing the resubmission of the New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021. Aquestive received a Complete Response Letter (CRL) from the FDA in September 2020, completed a Type A meeting with the FDA in November 2020 and received further guidance from the FDA in February 2021. Based upon the Agency's guidance, the submission included additional statistical modeling and supporting analyses of the existing clinical data. The Company continues to believe that no additional clinical studies will be required for FDA approval of Libervant for U.S. market access.

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 Statement

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, 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™, including our belief that the resubmitted NDA addresses all of the issues raised in the CRL, through the regulatory and development pipeline 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; risk of delays in FDA approval of Libervant 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 in obtaining such approval; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug product candidates 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 in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; 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; 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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