Aquestive Therapeutics to Join the Russell 3000® and Russell 2000® Indexes Effective June 28, 2024

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WARREN, N.J., June 18, 2024 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced its expected addition to the broad-market Russell 3000® and Russell 2000® Indexes at the conclusion of the 2024 Russell U.S. indexes annual reconstitution, effective at the open of U.S. equity markets on Monday, July 1, according to a preliminary list of additions posted Friday, May 24, 2024.

"We are honored that Aquestive is joining the Russell 3000 Index, which represents the 3,000 largest U.S. public companies," said Dan Barber, President and Chief Executive Officer of Aquestive. "Being included in the Russell 3000 and 2000 Indexes is a reflection of our success over the last twelve months and has multiple benefits, including increased awareness, visibility, and enhanced liquidity."

"In the past year, we have achieved several important milestones including the completion of a Pivotal Study for our product candidate Anaphylm™ (epinephrine) Sublingual Film which met all of our predefined primary and secondary endpoints, the FDA approval of Libervant™ (diazepam) Buccal Film for epilepsy patients 2-5 years old, and a capital raise of $77.5 million with notable institutional healthcare investors," continued Mr. Barber. "We remain on track with our supportive studies for Anaphylm and continue to anticipate meeting with the FDA shortly after completion of these studies. Moreover, the team is focused on expanding the Company's commercial infrastructure to support the anticipated launch of Anaphylm, if approved by the FDA, and of Libervant, which recently received FDA approval for epilepsy patients between ages two to five."

The annual Russell US Indexes reconstitution captures the 4,000 largest US stocks as of Tuesday, April 30th, ranking them by total market capitalization. Membership in the US all-cap Russell 3000® Index, which remains in place for one year, means automatic inclusion in the large-cap Russell 1000® Index or small-cap Russell 2000® Index as well as the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings, and style attributes. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. For more information on the Russell 3000® Index and the Russell indexes reconstitution, go to the "Russell Reconstitution" section on the FTSE Russell website.

About Aquestive
Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by its licensees in the U.S. and around the world, and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit **Aquestive.com** and follow us on LinkedIn.

About Anaphylm™ (epinephrine) Sublingual Film
Anaphylm is a polymer matrix-based epinephrine prodrug candidate product. The product is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. The "Anaphylm" tradename for AQST-109 has been conditionally approved by the United States Food and Drug Administration (FDA). Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate. In March 2024, Aquestive reported positive topline clinical data for the two-part, Phase 3, single-center, open-label, randomized study, which was designed to compare the pharmacokinetics (PK) and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine intramuscular (IM) injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The Company met all predefined primary and secondary PK endpoints in this study.

About Libervant™ (diazepam) Buccal Film
Libervant™ (diazepam) Buccal Film is the first and only FDA approved orally administered rescue product for the treatment of seizure clusters in patients ages two to five.

In April 2024, the FDA approved Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between 2 to 5 years of age. Libervant for patients between the ages of two to five years old is immediately available in 5mg, 7.5mg, 10mg, 12.5mg, and 15mg, and the Company is currently able to accept and fill non-Medicaid prescriptions for these pediatric patients.

The New Drug Application (NDA) for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients twelve years of age and older was tentatively approved by the FDA in August 2022 and is currently subject to an orphan drug market exclusivity block until January 2027 based on an FDA approved nasal spray product of another company.

Important Safety Information
Do not give Libervant™ to your child if your child is allergic to diazepam or any of the ingredients in Libervant or has an eye problem called acute narrow angle glaucoma.

What is the most important information I should know about Libervant?

- **Libervant is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
  - **shallow or slowed breathing,**
  - **breathing stops (which may lead to the heart stopping),**
  - **excessive sleepiness (sedation).**

Do not allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking Libervant with opioids affects your child.

- **Risk of abuse, misuse, and addiction.** Libervant is used in children 2 to 5 years of age. The unapproved use of Libervant has a risk for abuse, misuse, and addiction, which can lead to overdose and serious side effects including coma and death.
- **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in Libervant).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
  - **Your child can develop an addiction even if your child takes Libervant as prescribed by your child's healthcare provider.**
  - **Give Libervant exactly as your child's healthcare provider prescribed.**
  - Do not share Libervant with other people.
  - Keep Libervant in a safe place and away from children.
- **Physical dependence and withdrawal reactions. Libervant is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines**, including Libervant, can cause physical dependence and withdrawal reactions, especially if used daily. Libervant is not intended for daily use.
  - **Do not suddenly stop giving Libervant to your child without talking to your child's healthcare provider.** Stopping Libervant suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets any of these symptoms.
  - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
  - Physical dependence is not the same as drug addiction. Your child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- Do not give your child more Libervant than prescribed or give Libervant more often than prescribed.

Libervant can make your child sleepy or dizzy and can slow your child's thinking and motor skills.

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

Like other antiepileptic medicines, Libervant may cause suicidal thoughts or actions in a small number of people, about 1 in 500.

- **Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:**
  - thoughts about suicide or dying
  - new or worse depression
  - feeling agitated or restless
  - trouble sleeping (insomnia)
  - acting aggressive, being angry or violent
  - other unusual changes in behavior or mood
  - attempts to commit suicide
  - new or worse anxiety or irritability

    - an extreme increase in activity and talking (mania)
    - new or worse panic attacks
    - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

What are the possible side effects of Libervant?

- The most common side effects of Libervant are sleepiness and headache.
- These are not all the possible side effects of Libervant.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800 FDA-1088.

For more information about Libervant, talk to your doctor, and see Product Information: Medication Guide and Instructions For Use.

Forward-Looking Statement
Certain statements in this press release include "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 anticipated inclusion in the Russell 3000 and Russell 2000 Indexes and the awareness, visibility, and enhanced liquidity they can bring to the Company, the advancement and related timing of the Company's product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including for expected clinical trials and meetings with the FDA , the expansion of our commercial infrastructure to support the launch of Libervant for epilepsy patients between 2 to 5 years of age and for Anaphylm, should we received FDA approval of Anaphylm, and other statements that are not historical facts.

These forward-looking statements are based on the Company's 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 its product development activities and clinical trials for Anaphylm; risk of the Company's ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's pivotal PK study trial protocol and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm at all; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product candidate Anaphylm and of Libervant for epilepsy pages aged two to five; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for pediatric epilepsy patients between 2 and 5 years of age; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for Anaphylm and commercial activities for Libervant and Anaphylm, should Anaphylm receive FDA approval; risk of the success of any competing products including generics; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the Securities and Exchange Commission. 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 the Company or any person acting on its 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.

Investor Inquiries:
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282