Aquestive Therapeutics and Haisco Pharmaceutical Group Enter Licensing and Supply Agreement for Riluzole Oral Film for ALS Treatment in China

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WARREN, N.J., March 03, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, announced the execution of a License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd. (SZSE: 002653) ("Haisco"), a pharmaceutical company based in the People's Republic of China ("China"), for Haisco to develop and exclusively commercialize EXSERVAN™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis ("ALS") in China.

Around 85% of ALS patients suffer from a progressive loss of bulbar functionality.[1] Swallowing food and liquids becomes more difficult over time. While most patients initiate on riluzole, some choose to discontinue treatment at various points in the disease progression due to an inability to swallow a tablet. EXSERVAN™ is designed to provide a meaningful treatment option, using Aquestive's orally administered PharmFilm® dosage form, to patients and caregivers. It alleviates the need for swallowing a tablet and water, while having a negligible impact on volume and viscosity of normal saliva.

"This agreement with Haisco will allow ALS patients in China to access EXSERVAN, a riluzole oral film, which will provide a meaningful treatment option to those who have to discontinue their treatment because of difficulties swallowing a tablet. This collaboration perfectly aligns with our mission to design patient-preferred medicines for their safety, efficacy, and ease of use," remarked Keith Kendall, Chief Executive Officer of Aquestive.

Pursuant to the agreement, Haisco will lead the regulatory and commercialization activities for EXSERVAN in China. Aquestive will serve as the exclusive sole manufacturer and supplier for the product. Aquestive will receive a $7million upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of EXSERVAN in China, and will earn manufacturing revenue as the exclusive supplier of EXSERVAN.

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[1] Difficulty Swallowing - ALS News Today

About Aquestive Therapeutics
Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products in the U.S. and around the world. 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, or CNS, 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 Haisco
Haisco Pharmaceutical Group is a China-based public pharmaceutical company dedicated to providing the best medical products in specialized area to patients and our community. With extensive experience, Haisco is capable of developing, manufacturing and commercializing innovative drug products as well as generic drug products with high technical barrier in our focused areas.

About EXSERVAN ™ (riluzole oral film)
EXSERVAN, an oral film formulation of riluzole, was developed by Aquestive using its PharmFilm® innovative drug delivery technology. The oral film is placed on the patient's tongue and quickly dissolves without the need for liquids or food. RILUTEK® (riluzole) tablets was the reference product during the oral film development. Oral film riluzole was approved by the U.S. Food and Drug Administration (FDA) in November 2019. Aquestive has entered into separate license and supply agreements for EXSERVAN in Europe with Zambon S.p.A. and in the Unites States with Mitsubishi Tanabe Pharma America.

IMPORTANT SAFETY INFORMATION
EXSERVAN™ (riluzole) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).
Do not use if you are allergic to riluzole or to any of its ingredients.

Before using EXSERVAN, tell your healthcare provider about all the medicines you take and all your health conditions, including if you:

- Have hepatic (liver) impairment.
- Are taking strong or moderate CYP1A2 inhibitors such as ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, zileuton.
- Are pregnant or intend to become pregnant during EXSERVAN therapy, or if you are breastfeeding or intend to breastfeed during EXSERVAN therapy.

EXSERVAN can cause serious side effects, including:

- **Hepatic Injury:** Cases of drug-induced liver injury, some fatal, have been reported in patients taking riluzole. Consult your healthcare provider promptly if you experience unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine.
- **Neutropenia:** Tell your healthcare provider if you develop a fever while taking EXSERVAN.
- **Interstitial Lung Disease:** Tell your healthcare provider if you have respiratory symptoms such as dry cough and difficult or labored breathing. Discontinue EXSERVAN immediately if interstitial lung disease develops.

The most common side effects include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.

These are not all the possible side effects of EXSERVAN. Consult your healthcare provider for medical advice about side effects and if you have any side effect that bothers you or that does not go away. To report SUSPECTED ADVERSE REACTIONS, contact Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Use EXSERVAN as prescribed. The recommended dosage for EXSERVAN is 50 mg taken orally twice daily at least 1 hour before or 2 hours after a meal. Place EXSERVAN oral film strip on the top of the tongue where it will adhere and dissolve. Do not cut or split the film or take liquids with EXSERVAN. Do not chew, spit, or talk while EXSERVAN is dissolving.

Forward Looking Statement
This news release contains forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, the review processes and other governmental regulation in China, Haisco's and Aquestive's abilities to successfully develop and commercialize drug candidates, including Exservan, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in Aquestive's most recent filings with the Securities and Exchange Commission. Aquestive undertakes no duty to update forward looking statements.

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