AVISE® Lupus Test Demonstrates Statistically Significant Clinical Utility in Achieving a Definitive SLE Diagnosis and Positively Impacts Treatment Decisions

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SAN DIEGO, July 13, 2021 (GLOBE NEWSWIRE) -- Exagen Inc. (Nasdaq: XGN), a leading provider of autoimmune testing solutions, announced today the publication of their latest clinical utility study in Lupus & Science Medicine, found here: https://lupus.bmj.com/content/8/1/e000528.full. This multi-center study demonstrated that the AVISE Lupus test helped increase confidence in ruling-in and ruling-out systemic lupus erythematosus (SLE) in patients suspected of this disease and informed appropriate treatment decisions.

In collaboration with 12 rheumatology practices, a systematic and longitudinal review of medical records of patients that received AVISE testing between 2018 and 2020 was performed. Medical records of antinuclear antibody (ANA)-positive patients with a positive or negative AVISE Lupus score were evaluated at three time points: when the test was ordered, when the test results were reviewed, and at least 8 months later.

Assessment of the confidence in the diagnosis of SLE and initiation of hydroxychloroquine (HCQ) showed that the AVISE Lupus test impacted physician behavior. In particular, physician certainty in an SLE diagnosis increased with increasing AVISE Lupus scores. Similarly, certainty in an SLE diagnosis decreased when an AVISE Lupus score was negative, indicating that the test helped in both ruling-in and in ruling-out the disease. AVISE Lupus also helped make an accurate diagnosis, both early on and during the course of the study, and higher AVISE Lupus scores led to an increased initiation of HCQ treatment, demonstrating the potential utility of the test in impacting patient management by informing appropriate treatment decisions.

Exagen President and CEO, Ron Rocca, shared, “We are thrilled to share the publication of another great study demonstrating the clinical utility of our AVISE testing. With patients at the forefront of our minds, we will continue to support rheumatologists in the diagnosis of SLE and other debilitating autoimmune diseases for their patients.”

About Exagen Inc.

Exagen is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. Exagen has developed and is commercializing a portfolio of innovative testing products under its AVISE® brand, several of which are based on our proprietary Cell-Bound Complement Activation Products, or CB-CAPs, technology. Exagen’s goal is to enable providers to improve care for patients through the differential diagnosis, prognosis, and monitoring of complex autoimmune and autoimmune-related diseases, including rheumatoid arthritis and lupus. For further information please visit www.exagen.com.

Forward Looking Statements

Exagen cautions you that statements in this press release that are not a description of historical facts are forward-looking statements. These statements are based on Exagen's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements about Exagen’s goals and strategies, regarding the potential utility and effectiveness of Exagen’s services and testing solutions and regarding Exagen’s interpretation of clinical study results and management’s views and evaluations of the same. The inclusion of forward-looking statements should not be regarded as a representation by Exagen that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Exagen’s business, including, without limitation: the COVID-19 pandemic may continue to adversely affect our business, financial condition and results of operations, including as a result of shutdowns of our facilities and operations as well as those of our suppliers and courier services, impeding patient movement and interruptions to healthcare services causing a decrease in test volumes, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, and delays in ongoing and planned clinical trials involving our tests; the company’s commercial success depends upon attaining and maintaining significant market acceptance of its testing products and promoted therapeutics among rheumatologists, patients, third-party payors and others in the medical community; the company’s ability to successfully execute on its Dx/Rx strategy; third party payors not providing coverage and adequate reimbursement for the company’s testing products or promoted therapeutics; the company’s ability to obtain and maintain intellectual property protection for its testing products; regulatory developments affecting the company’s business; and other risks described in the company’s prior press releases and the Exagen’s filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended December 31, 2020 on and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Exagen undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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