Exagen Inc. Completes Validation and Regulatory Submission for New Lupus and Rheumatoid Arthritis Biomarkers on the AVISE® CTD Platform

November 14, 2024 at 4:30 PM EST

Significant enhancements will equip clinicians with even more diagnostic clarity in the treatment of patients with autoimmune disease

CARLSBAD, Calif., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Exagen Inc., a leading provider of autoimmune testing, today announced the validation and regulatory submission for approval of new Systemic Lupus Erythematosus (SLE) and rheumatoid arthritis (RA) biomarkers, to be incorporated into the AVISE CTD platform. Collectively, these new biomarkers will further improve the clinical utility of AVISE CTD, providing clinicians with the information they need to definitively diagnose patients and shorten their autoimmune diagnostic journeys.

Since 2012, AVISE CTD has delivered diagnostic clarity where overlapping clinical symptoms and ambiguous disease states make it difficult to arrive at a differential diagnosis of a connective tissue disease (CTD). A lack of diagnostic clarity may lead to serial and repeat testing, increased morbidity, worsening mortality rates and growing healthcare costs.

“The AVISE CTD enhancements are a direct result of our continuing commitment to develop and deliver testing solutions that address the challenges of clinicians searching for answers for suspected autoimmune patients,” said John Aballi, CEO, Exagen. “These coming enhancements exemplify how Exagen is raising the bar for autoimmune diagnostic testing while also empowering clinicians to deliver better patient care.”

The seven new biomarkers for AVISE CTD are as follows:

- **A new T Cell Lupus profile will include three new T Cell biomarkers (TC4d, TIgG, TIgM).**

These provide enhanced sensitivity for SLE as compared to conventional SLE biomarkers and serve as a complement to the AVISE Lupus profile also included in the test.

- **The RA profile will be enhanced with the addition of four biomarkers (anti-CarP and anti-RA33 biomarkers IgA, IgG, IgM).**

Providers are given more data to confidently identify patients with RA and substantiate a seronegative RA diagnosis.

The AVISE CTD test that rheumatologists have come to know and trust is composed of multiple biomarker assays that assist in the clinical diagnosis of the most common CTDs, which included:

- SLE
- RA
- Sjögren's Disease
- Mixed Connective Tissue Disease (MCTD)
- Antiphospholipid Syndrome
- Myositis
- Systemic Sclerosis
- Graves’ Disease
- Hashimoto’s Thyroiditis

“The addition of these biomarkers to the AVISE CTD test is an important milestone for those of us working with suspected autoimmune patients,” said Vasileios Kyttaris, MD, PhD, FACR. “We as clinicians now have an even clearer window into each individual patient’s health, which in turn may lead to a more definitive diagnosis.”

Availability of the AVISE CTD test enhancements are pending conditional approval by the New York State Department of Health. Learn more about AVISE CTD and its ability to provide unique diagnostic clarity.

About Exagen Inc.

Exagen Inc. (Nasdaq: XGN) is a leading provider of autoimmune diagnostics, committed to transforming care for patients with chronic and debilitating autoimmune conditions. Based in San Diego County, Calif., Exagen’s mission is to provide clarity in autoimmune disease decision making and improve clinical outcomes through its innovative testing portfolio. The company’s flagship product, AVISE ® CTD, enables clinicians to more effectively diagnose complex autoimmune conditions such as lupus, rheumatoid arthritis, and Sjögren’s disease earlier and with greater accuracy. Exagen’s laboratory specializes in the testing of rheumatic diseases, delivering precise and timely results, supported by a full suite of AVISE-branded tests for disease diagnosis, prognosis, and monitoring. With a focus on research, innovation, education, and patient-centered care, Exagen is dedicated to addressing the ongoing challenges of autoimmune disease management. For more information, visit Exagen.com or follow @ExagenInc on X.

Forward Looking Statements

Exagen cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements.

These statements are based on Exagen's current beliefs and expectations. 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 Exagen's goals, strategies and ambitions; potential future financial and business performance; the potential for Exagen's research to lead to positive impacts to patients; the potential for Exagen's research to lead to new or improved testing products; the potential utility and effectiveness of Exagen's services and testing solutions; the potential value of updates being made to AVISE® CTD; potential shareholder value and growth and 2024 guidance. 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: 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 its tests; changes in laws and regulations related to Exagen's regulatory requirements; Exagen's commercial success depends upon attaining and maintaining significant market acceptance of its testing products among rheumatologists, patients, third-party payors and others in the medical community; Exagen's ability to successfully execute on its business strategies; third-party payors not providing coverage and adequate reimbursement for Exagen's testing products, including Exagen's ability to collect on funds due; Exagen's ability to obtain and maintain intellectual property protection for its testing products; regulatory developments affecting Exagen's business; and other risks described in Exagen's prior press releases and Exagen's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in Exagen's Annual Report on Form 10-K for the year ended December 31, 2023 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.

Contact:
Ryan Douglas
Exagen Inc.
ir@exagen.com
760.560.1525

Source: Exagen Inc.