Exagen®

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Exagen Announces Publication of Two Key Studies Validating Clinical Performance of AVISE® Lupus in Patients with Probable SLE and Demonstrating Superior Clinical Utility Compared to Standard Diagnostic Testing

First ever prospective randomized multicenter clinical utility study shows the favorable impact of AVISE® Lupus on clinical decision-making and patient management

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SAN DIEGO, CA – Exagen Inc. (Nasdaq: XGN), an organization dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention, today announced the publication of two key studies. Collectively, the studies further validate that the information contained in the AVISE® Lupus test positively impacts physician clinical decision-making and demonstrated the patented test and algorithm helped predict those patients with early signs of systemic lupus erythematous (SLE) that are likely to transition to classifiable SLE according to American College of Rheumatology (ACR) criteria.

"With these studies, Exagen has documented what many physicians already know, and that is the AVISE® Lupus test really helps physicians improve their ability to diagnose and manage patients suspected of an autoimmune disease," shared study author Daniel Wallace MD, FACP, MACR, a board-certified internist and rheumatologist who serves as Clinical Professor of Medicine at the David Geffen School of Medicine at UCLA, and Associate Director of the Rheumatology Fellowship Program at Cedars-Sinai Medical Center.

The CARE for Lupus Clinical Utility study, a *randomized, prospective, multi-site trial to assess the clinical utility of multianalyte assay panel with complement activation products for the diagnosis of SLE*, was published in Lupus Science & Medicine. The prospective study shows results of 145 patients with a positive anti-nuclear antibody (ANA) test referred to a Rheumatologist for the suspicion of a connective tissue disease. Patients were randomized to investigators from 32 academic and community sites which compared the use of the AVISE® Lupus test to standard diagnosis laboratory testing (SDLT). The results showed a statistically significant difference ($p<0.05$) in the physician reported likelihood of SLE in the AVISE® Lupus arm compared to the SDLT alone. In addition, for those patients who had a positive AVISE® Lupus test result, the physicians were more likely ($p=0.034$) to initiate therapy for SLE, specifically prednisone.

The CLASS Clinical Validation study, *Complement activation occurs in patients with probable systemic lupus erythematosus and may predict progression to ACR classified SLE*, was published in Arthritis & Rheumatology. This second clinical validation study included a total of 246 subjects including 92 probable SLE (pSLE) patients and showed that more pSLE were positive for CB-CAPs (28%) or AVISE® Lupus (40%) than for low complement (9%) at the enrollment visit ($p = 0.0001$, for each). In pSLE, an AVISE® Lupus index value of > 0.8 at enrollment predicted fulfillment of a fourth ACR criterion within 18 months (hazard ratio = 3.11, $p<0.01$).

“We are very pleased with the outcome of these studies and we are proud to be leading the way with the first-ever clinical utility studies for novel biomarkers in SLE,” shared Ron Rocca, President and CEO of Exagen Inc. who added, ”We work very closely with all stakeholders in today’s healthcare environment and we understand that our AVISE® Lupus test must meet the needs of each group in order to be widely adopted. We believe these studies, combined with our prior evidence, demonstrates that AVISE® Lupus is clinically validated in both diagnosed and pSLE patients, has proven clinical utility for providers and their patients, while providing a net savings to the healthcare system through improved outcomes and reduced hospital visits.”

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 rheumatologists to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and rheumatoid arthritis.

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 the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the results of these clinical utility studies validating the AVISE® Lupus test and the potential to lead to increased adoption of the AVISE® Lupus test; and the ability of the AVISE® Lupus test to help physicians improve their ability to diagnose and manage patients suspected of an autoimmune disease and provide net savings to the healthcare system. 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 commercial success depends upon attaining and maintaining significant market acceptance of its testing products and promoted therapeutics among rheumatologists, patients, third-party payers and others in the medical community; if third-party payers do not provide coverage and adequate reimbursement for Exagen’s testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for its testing products or promoted therapeutics, or if Exagen or its partners are unable to successfully negotiate payer contracts, Exagen’s commercial success could be compromised; and other risks described in the Company’s prior press releases and in the Company’s filings with the Securities and Exchange Commission, including under the heading "Risk Factors" in the Company’s Registration Statement on Form S-1 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 we undertake no obligation to revise or update this press release to reflect events or circumstances 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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