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Exagen Inc. and Queen Mary University of London Announce Exclusive License and Collaboration to Develop Novel Patented Molecular Signatures for Rheumatoid Arthritis Biologic Therapeutic Selection

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SAN DIEGO, Jan. 09, 2022 (GLOBE NEWSWIRE) -- Exagen Inc. (Nasdaq: XGN), a leading provider of autoimmune testing solutions, and Queen Mary University of London, announced today the execution of a research collaboration and exclusive license agreement. The collaboration will focus on development and optimization of patent-pending precision medicine approaches, based on RNA expression signatures, to personalize therapeutic agent selection for rheumatoid arthritis (RA) patients. Both parties will contribute to the development of the patent-pending assays, leading to the commercialization of novel molecular assays that segment patients according to gene expression in their synovial tissue biopsies.

RA is estimated to affect approximately two million patients in the United States and be twice as prevalent in women as in men and can be difficult to manage due to the variability in treatment response from patient to patient. Therapeutic agent selection for RA patients remains a significant unmet need. RA patients often try multiple therapies empirically before they find one that lowers their disease activity. The placement of an RA patient on an ineffective therapy risks progression and worsening of the disease, further damage to the joints, and significant wasted spend on expensive therapeutic agents. There are currently no reliable assays for predicting positive patient response prior to the selection of commonly prescribed biological therapeutic agents.

Building on Prof. Costantino Pitzalis and Dr. Myles Lewis's molecular pathology definition of disease evolution and treatment response, Exagen has acquired an exclusive global license to a family of patent-pending assays pertaining to RNA expression patterns used in the prediction of patient response to commonly prescribed csDMARD and biological therapeutics for RA. The assays utilize minimally invasive synovial tissue biopsies as input, which are then assessed for RNA expression data. These data are then run through proprietary algorithms that provides actionable insights on predicted csDMARD and biological therapeutic response for RA patients based on an individual patient's RNA expression patterns.

Prof. Pitzalis, Versus Arthritis Professor of Rheumatology and Deputy Director at the William Harvey Research Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London stated, "I am excited to be part of this research collaboration with Exagen and am very much looking forward to contributing to the development of diagnostics aimed at bringing molecular pathology into clinical algorithms to better define the specific pathways driving disease diversity in individual patients. This would better inform clinicians on patients' prognosis and enhance their ability to make informed decisions on drug prescribing. Exagen's track record in bringing diagnostics to the market takes this opportunity to a completely new level, making the promise of precision medicine closer to clinical implementation."

Prof. Pitzalis is a leading authority on rheumatoid arthritis. He leads a team of 50 clinical researchers and is the author of over 300 peer-reviewed publications in the field of inflammation, immunity, and arthritis. Prof. Pitzalis formulated this groundbreaking approach to gene expression patterns together with Dr. Myles Lewis, head of the bioinformatics/biostatistics group at the Centre for Experimental Medicine and Rheumatology. "We are excited to work with Prof. Pitzalis and Dr. Lewis at Queen Mary University of London to accelerate the development of their highly-innovative RNA-based biomarker assays to better serve RA patients. Prof. Pitzalis is a well-respected thought leader in the field of arthritis research, and Exagen is enthusiastically looking forward to collaborating with his group to bring exciting and groundbreaking products forward to improve the care continuum for rheumatoid arthritis patients," said Ron Rocca, President and CEO of Exagen Inc. "Exagen is committed to developing and commercializing these assays to inform treatment decisions throughout the RA patient journey. We intend to market the new assays as AVISE® RADR (rheumatoid arthritis drug response)."

For further information on AVISE® RADR please visit https://exagen.com/tests/avise-radr/.

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.

About Queen Mary University of London and Queen Mary Innovation Ltd

Queen Mary University of London is a world-leading research-intensive university with over 28,000 students representing more than 160 nationalities.

A member of the prestigious Russell Group, we work across the humanities and social sciences, medicine and dentistry, and science and engineering, with inspirational teaching directly informed by our research.

In the most recent Research Excellence Framework, we were ranked 5th in the country for the proportion of research outputs that were world-leading or internationally excellent. We offer more than 240 degree programmes and our reputation for excellent teaching was rewarded with a silver in the 2017 Teaching Excellence Framework (TEF) awards.

Queen Mary Innovation Ltd (QMI) is Queen Mary's wholly-owned technology transfer company and is responsible for the commercialisation and

management of the University's intellectual property and portfolio of spinout companies. QMI protects and exploits Queen Mary's research-derived intellectual property and helps to maximise the economic and societal impact of that research. QMI's Associate Commercialisation Director Biopharma, Dr. Michele Hill-Perkins, led the negotiation and licence transaction for QMUL.

For further information on QMI please visit http://www.gminnovation.co.uk.

Forward Looking Statements

Exagen cautions you that statements 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. Such forward-looking statements include, but are not limited to, statements regarding the expected benefits of the collaboration with Queen Mary University of London and any potential development and commercialization of novel patented molecular signatures for diagnosis, prognosis and monitoring of autoimmune diseases. 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: developing new molecular signatures involves a lengthy and complex process, and the collaboration may not lead to novel patented molecular signatures or generate significant commercial testing products on a timely basis, or at all; the COVID-19 pandemic may continue to adversely affect our business, financial condition and results of operations, including our collaboration and development activities; risks associated with maintaining the collaboration and license agreement; and other risks described in the company'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 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. 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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