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# Exagen, Maker of AVISE Testing, Announces First Blood Test for Anti-CarP, a Breakthrough Biomarker for Rheumatoid Arthritis

Novel Test Now Available to Aid in Detection and Management of Widespread Debilitating Condition



San Diego, CA and Albuquerque, NM, Sep 11, 2018 (GLOBE NEWSWIRE) -Exagen Diagnostics, the leader in specialty rheumatology testing, announced today availability of the first validated blood test to detect autoantibodies against carbamylated proteins (anti-CarP). Studies show that this novel test can add valuable information in the management of Rheumatoid Arthritis (RA), a condition affecting over 1.3 million Americans.<sup>1</sup>

Elevated levels of anti-CarP antibodies are suggestive of a more severe form of RA, more than doubling the chance for joint erosions within 3 years of a diagnosis compared to those without elevated levels. In a retrospective study, positivity for anti-CarP has also been associated with the use of more aggressive forms of therapy, such as biologic agents, to help maintain control of the disease.<sup>2</sup>

Rheumatoid arthritis symptoms can progress rapidly and with little advance warning, leading to permanent and debilitating joint damage, so it is crucial that physicians stay ahead of the disease.<sup>3</sup> "Having an advanced test like anti-CarP may offer physicians additional insights to better manage their rheumatoid arthritis patients for improved healthcare outcomes" said Dr. Arthur Weinstein, Chief Medical Officer at Exagen Diagnostics. "There are a number of clinical scenarios where this test can add significant value, for example; when patients are feeling fine and elect to forego proactive therapy recommended by their provider, or when other lab tests such as anti-CCP or anti-RF are negative."

Dr. Thierry Dervieux, Chief Scientific Officer at Exagen explained, "Many laboratories stop short of demonstrating the clinical performance in their own population, however at Exagen we put in the extra effort to validate the performance of the test as we have done here for anti-CarP." According to Dr. Thomas Huizinga, Professor of rheumatology at Leiden University Medical Center where the marker was first characterized, "This marker may be the missing link to understanding why some patients have such severe and erosive disease and others experience mild symptoms. Furthermore, we have relied heavily on markers like rheumatoid factor and anti- cyclic citrullinated peptides which are very useful but do not tell the complete story."

"By continuing to bring innovative biomarkers like anti-CarP to the market, we are providing physicians the tools necessary to personalize care of those suffering from autoimmune rheumatic conditions," said Ron Rocca, Exagen's CEO. "As leaders in the rheumatology space it is logical that we are the first to introduce this novel marker that meets such an important unmet need. New product launches like this are key to maintaining our tremendous growth rate of over 30% per year for the past 5 years".

Exagen believes that by offering novel tests like anti-CarP, patients and physicians can obtain the meaningful clinical insight needed to support more informed decision-making and improve healthcare outcomes.

## References:

- 1. Shi J, et al. Autoantibodies recognizing carbamylated proteins are present in sera of patients with rheumatoid arthritis and predict joint damage. Proceedings of the National Academy of Sciences, 2012;108(42):17372-17377.
- 2. Truchetet ME, et al. Association of the presence of anti–carbamylated protein antibodies in early arthritis with a poorer clinical and radiologic outcome. Arthritis Rheumatology, 2017; 69(12): 2292-2302.
- 3. Verheul K, et al. The combination of three autoantibodies, ACPA, RF and anti-CarP antibodies is highly specific for rheumatoid arthritis: implications for very early detection of individuals at risk to develop rheumatoid arthritis. <u>Arthritis</u> <u>Rheumatol. 2018 May 21. doi: 10.1002/art.40562. [Epub ahead of print]</u>

## About Lupus and Rheumatoid Arthritis

Lupus and rheumatoid arthritis are autoimmune diseases in which the body attacks its own, healthy tissues and organs. Patients suffer joint pain along with increased risk for other life-threatening conditions. Systemic Lupus Erythematosus (SLE), a more severe form of lupus brings with it a host of unwanted symptoms including unexplained fevers, hair loss, fatigue, and skin rashes. Each year millions of Americans seek out a differential diagnosis for symptoms consistent with RA and SLE. Women are more likely to suffer from these conditions than men, and there's no definitive cause, though researchers suspect genes as well as environmental factors may play a role.

## About AVISE testing and Cell-Bound Complement Activation Products (CB-CAPs)

AVISE testing includes patented algorithms and biomarkers such as CB-CAPs (EC4d & BC4d), which are stable biomarkers of complement activation. Use of these proprietary measures has demonstrated superior performance in the differential diagnosis of connective tissue diseases (CTD), compared to standard biomarkers alone. Exagen measures deposits resulting from activation of the complement system using flow cytometry to quantify C4d which is covalently bound to circulating cells including erythrocytes and B cells.

#### About Exagen

Exagen is a commercial stage life sciences company that is patient focused and discovery driven. We serve patients and healthcare providers across the U.S. in the diagnosis, prognosis, and management of lupus, rheumatoid arthritis, and other autoimmune rheumatic conditions. By leveraging our patented and validated technology we can help get to the real cause of a patient's symptoms and guide their journey to improved health. For more information, visit <u>www.exagen.com</u> or follow us on <u>Facebook</u>, <u>Twitter</u>, <u>YouTube</u>, <u>LinkedIn</u>, or <u>Instagram</u>.

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