



NEW ANTIBODY DISCOVERED IN THE BLOOD OF MANY FIBROMYALGIA PATIENTS

Reactivity on the APA Assay Correlates with Fibromyalgia Severity in Many Patients

FOR IMMEDIATE RELEASE

NEW ORLEANS, February 10, 1999 - Autoimmune Technologies, LLC, a New Orleans biotechnology company, today announced that scientists have discovered a new antibody in the blood of many fibromyalgia patients. This research is described in an article entitled "Anti-Polymer Antibody Reactivity in a Subset of Patients with Fibromyalgia Correlates with Severity," which appears in the February 1999 issue of The Journal of Rheumatology, a prominent scientific journal.

Using a patented blood test called the Anti-Polymer Antibody Assay, or APA Assay, researchers found anti-polymer antibodies in approximately one-half of all patients who were diagnosed with fibromyalgia and in more than 60% of the fibromyalgia patients with severe fibromyalgia symptoms. Patients with diseases frequently confused with fibromyalgia, including rheumatoid arthritis, systemic lupus erythematosus, and systemic sclerosis/scleroderma, had a much lower incidence of these antibodies than did the fibromyalgia patients.

Fibromyalgia syndrome is a chronic pain disorder that affects millions of individuals, primarily women, in many countries throughout the world. The cause or causes of fibromyalgia are currently unknown, but researchers have suggested that trauma, infection, and exposure to environmental factors may all participate in the development of this debilitating illness. Together with widespread pain and tender points in various areas of the body, signs and symptoms include fatigue, sleep disorder, morning stiffness, headache, cognitive problems, and other symptoms. In the United States, some 3% to 5% of adult women meet the strict diagnostic criteria of the American College of Rheumatology for fibromyalgia, but as many as 15% to 20% of adult women may have fibromyalgia-like symptoms.

Fibromyalgia syndrome is often difficult to diagnose, and typically a diagnosis is reached through the time-consuming and expensive process of ruling out other illnesses that have similar symptoms. In addition, many physicians consider fibromyalgia to be the result of aging and other normal body processes and do not regard it as a distinct clinical disorder. The resulting reluctance on the part of some physicians to attribute their patients' symptoms to a specific illness has added considerably to the distress of many fibromyalgia patients. Until now, there has been no laboratory test to help identify fibromyalgia.

"Our results show that there is a unique immunological response in many fibromyalgia patients," said Russell B. Wilson, Ph.D., president of Autoimmune Technologies and lead investigator of the published study. "We hope that these findings will lead to a better understanding of the illness and to the development of treatments for these patients."

It is possible, Dr. Wilson pointed out, that anti-polymer antibodies are associated with one of the several different causes of fibromyalgia, perhaps the cause that tends to produce the most severe

symptoms. The published data indicate that this may be the case, although more research will be needed. In addition to serving as a marker for fibromyalgia, he noted, it is also possible that these antibodies are directly involved in initiating or promoting fibromyalgia.

The development of a laboratory test for fibromyalgia was welcomed by experts in the field.

"The fibromyalgia syndrome is common in clinical medicine and in the general community. We also have data on its cost," said I. Jon Russell, M.D., Ph.D., an internationally recognized fibromyalgia investigator and clinician from the University of Texas Health Center at San Antonio. "The direct medical costs of this disorder to the U.S. economy are over \$16 billion annually. The findings of this study raise the hopeful prospect that a new test will help us better understand fibromyalgia. Further research is needed to confirm the clinical specificity of the test relative to other painful conditions. In addition, it will be important to determine whether the antibody identified by this test in the blood of people with fibromyalgia is related to the cause of the disorder or simply represents an interesting epiphenomenon," Dr. Russell said.

Associated factors appear in parallel in epiphenomena. If further research shows the production of anti-polymer antibodies to be an epiphenomenon, the antibodies would serve as a laboratory marker for fibromyalgia without playing a direct role in the disease process.

Kristin Thorson is president of The Fibromyalgia Network, a patient self-help organization headquartered in Tucson, Arizona, and president of The American Fibromyalgia Syndrome Association, a charitable organization dedicated to funding research on fibromyalgia and chronic fatigue syndrome. "In the past," Ms. Thorson said, "many health insurance companies and some members of the medical community have argued that fibromyalgia is not real - all because no one had developed a lab marker to indicate otherwise. Now that there is a blood marker that can be shown to correlate with disease severity, there should be no more debate over the existence of fibromyalgia and scientists should be encouraged to research effective therapies for this potentially disabling illness."

Robert M. Bennett, M.D., a physician and scientist who is chairman of the Division of Arthritis and Rheumatic Disease of Oregon Health Sciences University in Portland and a widely published and internationally known expert on fibromyalgia syndrome, said "There are two major problems for most physicians in accepting fibromyalgia. The first is the lack of an easily performed laboratory test. The second is its recalcitrance to therapy. The promise of a potentially useful diagnostic marker is an exciting development in this field. If the sensitivity and specificity of this test can be confirmed by independent laboratories, it could open up an important new research avenue for a condition that compromises the quality of life of five million to ten million U.S. women."

Autoimmune Technologies expects during 1999 to apply to the U.S. Food and Drug Administration for approval of a kit form of the Assay as a diagnostic test. "The reproducibility of the APA Assay has already been independently demonstrated by the National Institute of Public Health and the Environment, or RIVM, in The Netherlands," said Dr. Wilson. "The RIVM has found the APA Assay to give reproducible results and to be useful for the evaluation of the presence of anti-polymer antibodies in human serum. The other confirmatory studies discussed by Drs. Russell and Bennett are already well under way. These studies, together with our research published in The Journal of Rheumatology, will be included in our application to the FDA for approval of the Assay as an in vitro diagnostic test to aid in the diagnosis of fibromyalgia."

Other authors of the article in this month's issue of The Journal of Rheumatology include Dr. Oscar S. Gluck and Dr. John R. P. Tesser of the Arizona Rheumatology Center in Phoenix, Dr. Janet C. Rice of Tulane University School of Public Health and Tropical Medicine, and Dr. Alan J. Bridges of the University of Wisconsin School of Medicine in Madison.

Anti-polymer antibodies were discovered by researchers at Tulane University Medical Center, where the APA Assay was developed. Autoimmune Technologies has licensed the APA Assay from Tulane. An APA Assay kit is not currently in commercial distribution in the U.S., although the Assay is being performed by Autoimmune Technologies as a service to physicians and researchers for investigational use only. A kit form of the APA Assay will be available in the near future in other countries.

The APA Assay is covered by U.S. and European patents, and patents in other countries are pending.

For further information, please visit www.autoimmune.com.

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