

### NASD (OTC BB) CONX

### FOR IMMEDIATE RELEASE

# **Corgenix and Autoimmune Technologies Complete Development of Diagnostic Product for Fibromyalgia**

## Test kit for anti-polymer antibodies (APA) to be launched this year through Corgenix distribution organization

WESTMINSTER, Colorado – August 19, 2004 -- Corgenix Medical Corporation (OTC BB: <u>CONX</u>) announced today that it has completed the development of the APA ELISA test kit for diagnosing fibromyalgia. The product was developed under a Development and Manufacturing Agreement with Autoimmune Technologies, LLC (Autoimmune), a New Orleans biomedical company. The new product employs Autoimmune's patented technology, and is expected to enter FDA clinical trials in the United States this September.

The Development and Manufacturing Agreement provides Corgenix with the exclusive rights to manufacture the kit, which detects anti-polymer antibodies (APA) and serves as the first serum-based assay specific for fibromyalgia, a common pain and fatigue disorder. Corgenix and Autoimmune are collaborating on distribution of the product, and expect to launch the patented APA ELISA test kit this September in Europe through Corgenix' international distribution network. International distribution will be coordinated by Corgenix' subsidiary in the UK. The product will subsequently be available in the US if the FDA grants regulatory clearance.

"Current data suggests that APA-positive fibromyalgia patients comprise the majority of fibromyalgia patients," said Luis Lopez, MD, Chairman and CEO of Corgenix. "This test is intended for use as an aid in the diagnosis of patients presenting with the symptoms and signs of fibromyalgia syndrome, as an aid in differentiating fibromyalgia patients from patients with other autoimmune diseases, and as an aid in determining which fibromyalgia patients have an immune response that is associated with their symptoms."

Fibromyalgia Syndrome (FMS) is a common chronic disorder that afflicts millions of individuals, primarily women. It appears to have multiple causes. FMS signs and symptoms include widespread pain, specific painful "tender points," fatigue, stiffness, sleep disturbance, headache, depression, anxiety, cognitive problems and other symptoms. Not all of the symptoms are present in every patient, and each patient may have different symptoms at different times. The American College of Rheumatology (ACR) criteria for fibromyalgia require that a patient manifest localized pain in at least 11 of 18 possible tender points and have a history of chronic widespread pain of greater than three months' duration. Clinical physicians often consider other symptoms as well when making a diagnosis of FMS. However, all of the diagnostic criteria now generally used for fibromyalgia are subjective, and this leads many people who aren't suffering from fibromyalgia to believe that FMS is a psychological disorder rather than a physical disorder.

"The APA Assay is the first specific clinical laboratory test for objectively identifying fibromyalgia patients," said Russell B. Wilson, PhD, President and Chief Science Officer of Autoimmune Technologies. "The APA ELISA test detects IgG anti-polymer antibodies in human serum. Research has shown that not only are these antibodies detected in the majority of fibromyalgia patients tested, but antibody titers also correlate with the severity of symptoms in these patients."

Between 2% and 5% of adult women in the US are believed to have received a diagnosis of fibromyalgia, but the total number of FMS sufferers might be far greater. Researchers have found that, although half of US women have

none of the 18 possible fibromyalgia tender points, approximately 20% of US women may have 6 or more of these tender points. Other research has determined that the direct medical costs of fibromyalgia, which include patient visits to multiple physicians to obtain a diagnosis, may exceed more than \$15 billion per year in the US alone.

In discussing the potential market for the APA ELISA test kit in the context of these figures, Doug Simpson, President of Corgenix, said "Although other laboratory markers exist, this is the only serum-based lab test that specifically picks up fibromyalgia patients. Research findings to date strongly suggest that fibromyalgia in APA-positive patients is associated with an abnormal immune system response. As a result, we expect the APA ELISA test to be useful not only in helping physicians make an initial diagnosis of fibromyalgia but also in indicating to them which of their fibromyalgia patients might benefit from one or more of the many existing drugs or therapies that modulate the immune system."

Mr. Simpson went on to say, "This is a very important step forward for both of our companies. Obtaining rights to this unique technology represents an excellent strategic fit for Corgenix, and expands our business base in markets that we currently serve. We see a very attractive market potential worldwide for this testing, and think this brings significant opportunity to our company. In addition, the relationship provides Autoimmune Technologies with access to a company with a global network to distribute its unique technology to the world markets."

"We are happy to be working with Corgenix in what we feel is a very important endeavor," said Michael D. Charbonnet, CEO of Autoimmune. "Not since the discovery of rheumatoid factors in the 1940s has a laboratory test had the potential to so dramatically change the perception of a medical disorder. Rheumatoid factors provided the earliest laboratory evidence that rheumatoid arthritis was a 'real disease' and led to dramatic advances in treatment for it. We believe that the APA Assay has the ability to do the same thing for fibromyalgia, formally establishing fibromyalgia as a separate and distinct physical disease and leading to greatly improved patient outcomes."

#### **About Corgenix**

Corgenix is a leader in the development and manufacture of anti-Phospholipid test kits and other unique diagnostic products for cardiovascular disease and thrombotic risk, being the first on the market with an FDA cleared assay for anti-Cardiolipin (aCL). The company is based in metropolitan Denver and is focused on the development of specialized diagnostic kits for immunology disorders, vascular diseases and bone and joint diseases. Corgenix diagnostic products are commercialized for use in clinical laboratories throughout the world. More information about the company can be found on its Web site, www.corgenix.com.

Corgenix has previously announced a planned merger with Genesis Bioventures, Inc., (Genesis) (AMEX:GBI), a biomedical corporation focusing on the development and marketing of novel diagnostics and therapeutics.

### **About Autoimmune Technologies**

Autoimmune Technologies is a privately held early-stage biomedical company based in New Orleans. Autoimmune has licensed several proprietary breakthrough research discoveries, including the APA Assay, from Tulane University School of Medicine and is working to make them commercially available to the medical community. More information about the company can be found on its Web site, www.autoimmune.com.

Statements in this press release that are not strictly historical facts are "forward looking" statements (identified by the words "believe", "estimate", "project", "expect" or similar expressions) within the meaning of the Private Securities Litigation Reform Act of 1995. These statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, continued acceptance of the Company's products and services in the marketplace, competitive factors, changes in the regulatory environment, and other risks detailed in the Company's periodic report filings with the Securities and Exchange Commission. The statements in this press release are made as of today, based upon information currently known to management, and the company does not undertake any obligation to publicly update or revise any forward-looking statements.

For more information, contact: Corgenix: William Critchfield, CFO; (303) 453-8903; <u>wcritchfield@corgenix.com</u> Autoimmune Technologies: Michael D. Charbonnet, CEO; (504) 529-9944; <u>mdc@autoimmune.com</u> *SOURCE: Corgenix Medical Corporation*