



# CHRONIX BIOMEDICAL

Routine Serum DNA Blood Tests  
for Early Cancer Diagnosis and Management

## **CHRONIX BIOMEDICAL SAYS THREE RECENT STUDIES SUPPORT THE UTILITY OF CIRCULATING DNA AS NOVEL DIAGNOSTICS FOR HUMAN CANCER, MAD COW DISEASE AND OTHER CONDITIONS**

**-Study in Clinical Chemistry Demonstrates Feasibility of Identifying and Categorizing Circulating Nucleic Acids-**

**-Studies in Nucleic Acids Research and Blood Support Potential Diagnostic Applications in Mad Cow Disease and Human Cancer-**

San Jose, California, March 10, 2009 – Chronix Biomedical - developing and applying proprietary techniques to detect and analyze circulating nucleic acid sequences for the diagnosis and management of disease - today reported that three recent studies published in peer-reviewed journals have further confirmed the potential diagnostic and prognostic utility of fragments of DNA and RNA that circulate in the blood, known as circulating nucleic acids (CNAs). Data from these studies confirm previous findings showing that CNAs can identify the presence of certain diseases in blood samples months to years before clinical symptoms appear.

“The recent publication of these three studies represents a major milestone in the recognition of CNAs as novel diagnostic tools,” said Howard Urnovitz, Ph.D., CEO of Chronix. “Our ability to accurately identify and characterize the presence of significant differences in CNA levels and sequences between healthy and diseased individuals demonstrates how CNAs would be used for diagnosis and disease management in conditions as diverse as bovine spongiform encephalopathy (mad cow disease) and human cancers.”

In the study appearing in the current online edition of *Clinical Chemistry*, scientists from Chronix applied ultra-high speed sequencing technology and proprietary data analysis tools to characterize and categorize the CNA markers present in multiple individuals. The resulting databases of CNAs associated with specific disease states can be used to identify persons with undiagnosed disease, and potentially, to track changes in disease status. For example, the study found that one of the presumed healthy volunteers was actually infected with hepatitis B.

This study follows publication in January of research from scientists at the University of Calgary, Canada, the University of Göttingen, Germany and Chronix showing the ability of a simple blood test based on circulating DNA sequences to identify the presence of bovine spongiform encephalopathy (BSE) and the related condition chronic wasting disease (CWD) in live animals long before symptoms were evident. This advance is especially significant since BSE can now only be confirmed by examining the brain tissue of dead animals. Following expected confirmation in larger studies, this new approach could revolutionize testing for BSE, making it economically and logistically feasible to screen all cattle in the food chain before BSE symptoms appear. The study was published in the journal *Nucleic Acids Research*.

A third reported study highlights the potential utility of CNAs in the management of cancer. Dr. Urnovitz, and Brian G.M. Durie, M.D., Medical Director and co-founder of the International Myeloma Foundation, identified specific DNA sequences circulating in the blood of a patient with the bone marrow cancer multiple myeloma and tracked variations in these sequences as the patient's myeloma moved in and out of remission. There was also an unexpected finding when CNAs identified the development of a secondary cancer in this patient, before it was clinically apparent. This preliminary study is significant because it shows that CNAs can potentially be used to diagnose, monitor and manage cancer treatment. The abstract reporting this data was published in the journal *Blood* in connection with the December 2008 meeting of the American Society of Hematology.

"This approach opens the door to a new tool that will enable us to follow the progress of cancer treatment and give us an early warning when a myeloma patient is about to come out of remission," said Dr. Durie. "This will allow us to stay ahead of the disease instead of waiting for the patient to get sick before we can act. That capability will represent a major change in the way we treat this cancer."

Dr. Urnovitz concluded, "Even in these experiments we found unexpected results – undiagnosed hepatitis in one patient and a secondary cancer in another – confirming the utility of CNAs in finding unsuspected disease. With these multiple proof-of-concept experiments now completed, we are embarking on the studies needed to further confirm and commercialize this powerful new approach with important applications in personalized medicine and human health."

Chronix intends to work with a number of industry partners to develop and commercialize its CNA technology for diagnostic and prognostic applications. These emerging markets for novel genetic-based assays have multi-billion dollar potential. Because the Chronix technology can identify early changes in disease status, it also can be used to generate surrogate measures for drug development studies aimed at distinguishing responder and non-responder patient subgroups. The company has recently initiated discussions with potential pharmaceutical partners.

#### **About Chronix Biomedical**

Chronix Biomedical is pioneering a breakthrough approach to the diagnosis and management of chronic diseases and cancer. It has developed proprietary technology that measures and categorizes circulating nucleic acids, DNA sequences circulating in the blood that are associated with specific changes in disease and health status. Using advanced genome analysis methods, proprietary data tools and disease-specific databases, Chronix has demonstrated the utility of its diagnostic and prognostic approach in mad cow disease and multiple myeloma, and studies in other diseases are underway. The company plans to collaborate with a variety of partners to develop and market its DNA-based assays that have the potential to transform the management of a broad range of cancers and other conditions. Chronix is headquartered in San Jose, California and has research facilities in Germany.

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