



**For Immediate Release**

**ImmuneNetics Receives \$3.7 Million NIH Contract for Babesia Blood Screening Test**

***— Will Carry Out Clinical Trials with Blood Systems Research Institute, Creative Testing Solutions —***

**BOSTON — September 10, 2012** — ImmuneNetics, Inc., has received a \$3.7 million, two year SBIR contract from the National Heart, Lung and Blood Institute, an agency of the National Institutes of Health (NIH), to support clinical trials of a new blood screening test for Babesia infection.

"Babesia is among the top infectious threats to blood safety and, at present, there is no licensed test available. The NIH contract will allow us to address this gap in blood safety with the first cost-effective test designed for high-throughput screening of the blood supply. We are honored to have been entrusted by NIH to carry out this public health mission," said Andrew E. Levin, Ph.D., ImmuneNetics Chief Executive Officer and Scientific Director.

Babesia is a parasite which is transmitted by the same ticks that transmit Lyme disease. While it is often asymptomatic in healthy people, Babesia infection can lead to severe or fatal illness, especially in immunocompromised patients. The parasites can remain viable in blood donations and infect transfusion recipients. In recent years, nine fatal cases of transfusion-transmitted babesiosis have been reported. Surveillance carried out by the Centers for Disease Control and Prevention (CDC) revealed over 1,000 cases of infection nationwide in 2011 — a number that appears to be growing. The US Food & Drug Administration (FDA) sponsored a workshop in 2008 focused on Babesiosis as an emerging threat to the blood supply, and the Blood Products Advisory Committee convened a meeting in 2010 to advise the FDA on approaches to blood screening for Babesia.

The contract award will enable ImmuneNetics to bring its Babesia test, developed under initial NIH support, through clinical trials and regulatory licensure. The trials will be carried out in collaboration with Blood Systems Research Institute of San Francisco, Calif., and Creative Testing Solutions of Tempe, Ariz. Creative Testing Solutions currently tests about 25% of the US blood supply, including regions endemic for the parasitic agent. The Babesia test will initially be made available through Creative Testing Solutions' laboratories.

"We look forward to partnering with ImmuneNetics and BSRI in the development and FDA approval process of a Babesia assay for use in blood screening," said Creative Testing Solutions President Sally Caglioti. "It is always our intent to offer innovative services that provide our customers with the best donor testing possible. Active collaboration in the development of diagnostic tests that fit the immediate needs of the blood banking community is the next logical step to support CTS' mission."

"When the screening test identifies antibody-reactive donors, we will enroll and conduct rigorous testing of donation-derived and follow-up samples from those donors so that we can more fully understand the natural history of Babesia infection in asymptomatic donors," said Michael P. Busch, M.D., Ph.D., Blood Systems Research Institute Director and Senior Vice President for Research and Scientific Affairs at Blood Systems. "The information that we derive will help guide the development of policies on how the test can be used most effectively. It will also determine whether and how donors who have had a positive result on the screening test could safely donate in the future."

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For more information, visit the company's website at <http://www.immunetics.com> or call 1-617-896-9100 or toll-free 1-800-227-4765.

Immunetics is a leading developer and provider of innovative tests for a variety of bacterial, viral, and parasitic diseases. Recently, the company received FDA clearance for its BacTx<sup>®</sup> test for bacterial contamination in platelets. The company has developed and markets other FDA-cleared products, including a test for Lyme disease, and is actively working on new tests for HIV and Chagas disease — both of which are known or emerging risks to the blood supply.

### **About Immunetics**

Immunetics Inc. (<http://www.immunetics.com>) offers state-of-the-art assay technology for infectious disease diagnosis and blood screening, and for more than ten years has been a leading innovator of tests for bacterial, viral, and parasitic diseases. The company produces and markets a range of infectious disease assay kits and instruments. Its mission is to deliver better, cost-efficient care through more accurate diagnosis. Immunetics is headquartered in Boston. Follow Immunetics on Twitter at <http://twitter.com/immunetics>.

### **About Creative Testing Solutions**

Creative Testing Solutions ([www.myCTS.org](http://www.myCTS.org)), a joint venture of Blood Systems and Florida-based OneBlood, is the largest independent blood donor testing laboratory in the United States, specializing in high-volume blood donor testing and infectious disease reference work. This non-profit organization, headquartered in Tempe, Arizona, tests nearly 4.5 million samples annually at three national laboratories in Dallas, Phoenix and Tampa that, combined, provide testing for more than 25 percent of the U.S. blood supply.

### **About Blood Systems**

Blood Systems ([www.bloodsystems.org](http://www.bloodsystems.org)) is one of the nation's oldest and largest non-profit community blood service providers and operates community blood centers serving more than 500 hospitals in 18 states, biological products distribution services, a quality consulting group and a world-renowned transfusion medicine research institute.

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