

# Genalyte Expands into Cancer Profiling with \$1 Million NCI Grant to Develop Cancer Biomarker Panel; Establishes Collaborations with Three Cancer Research Centers

Collaboration will Assemble and Validate a Tumor Antigen-Associated (TAA) Autoantibody Biomarker Panel for Tumor Characterization and Cancer Immunotherapy

TAA Autoantibody Panels May Have Potential to Detect Cancer at Early Stage

Genalyte's Maverick™ System's Multiplexed Panels Can Simultaneously Measure Multiple Autoantibodies Rapidly and Accurately

**SAN DIEGO, OCTOBER 18, 2013** –Genalyte, Inc., today announced that it has received a \$1 million SBIR grant from the National Cancer Institute (NCI) to develop a biomarker panel to profile tumor antigen-associated (TAA) autoantibodies. The panel will run on Genalyte's multiplexed Maverick™ Detection System, which provides rapid, accurate, robust and scalable detection of proteins and nucleic acids with little or no need for sample preparation, using a single drop of blood or serum.

This project will develop a test that allows researchers to profile and monitor cancer-associated immune responses with a simple and rapid blood test. In the body, cancer cells are recognized by the immune system, which mounts a response in an effort to prevent their growth. This early warning system has value for stratifying cancer types and for monitoring disease progression and the effect of therapy. TAA autoantibodies have also demonstrated the potential to detect cancer early, when the chances for successful treatment are greatest.

Genalyte will collaborate with researchers at MD Anderson Cancer Center, Providence Cancer Center and Wayne State University to select and validate the biomarkers to be included in the panel.

Martin Gleeson, PhD, Chief Scientific Officer of Genalyte, noted, "Individual cancer biomarkers have been identified, but they do not provide an adequate level of specificity. Recent advances in immunotherapy highlight the role of the immune system in responding to and combating cancer. This grant will allow us to assemble high priority immune system-associated biomarkers into a panel with the aim of providing true detection value with enhanced specificity to researchers and ultimately, clinicians and patients."

In contrast to traditional biomarker assays, the Maverick system is highly automated and incorporates rigorous quality control, which will enable biomarker testing to become standardized and reproducible. This would allow researchers working in different labs to use each other's data, with the goal of speeding progress in personalized medicine, cancer immunotherapy and cancer diagnostics.

Martin “Mac” Cheever, MD, Director of the Cancer Immunotherapy Trials Network at the Fred Hutchinson Cancer Center, is serving as an advisor to the project. Dr. Cheever led an NCI pilot project to prioritize cancer-related antigens as targets for immunotherapy, which produced a list of 75 antigens that will be assessed in the new effort.

Dr. Cheever commented, “The technology developed at Genalyte holds great potential as a novel tool to monitor immune responses to cancer antigens. This effort to characterize antigens as functional targets in patients could help accelerate progress in cancer immunotherapy.”

Cary Gunn, PhD, CEO of Genalyte, noted “This exciting project is a natural extension of our capability to monitor blood biomarkers and exemplifies the potentially transformational capabilities of the Maverick system for research and clinical applications.”

Collaborators on the project include Felix Fernandez-Madrid, MD, PhD, a professor at Wayne State University School of Medicine and a member of the Karmanos Cancer Institute and Center for Molecular Medicine and Genetics; Keith Bahjat, PhD, Chief, Laboratory of Immunologic Monitoring, Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute at Providence Cancer Center; and Filip Janku MD, PhD, and Jennifer Jane Wheler, MD, both Assistant Professors, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine at MD Anderson Cancer Center.

For more information, visit [www.genalyte.com](http://www.genalyte.com). Maverick assays are available for research use only.

## **About Genalyte**

Founded in 2007, Genalyte, Inc., is commercializing the Maverick™ Detection System based on the company’s revolutionary Microring Sensor Technology™, a new approach to multiplexing that uses a silicon chip containing arrays of photonic ring sensors to reduce or eliminate sample preparation and provide scalable multiplexing for both proteins and nucleic acids. The one-step workflow of the Maverick System can deliver accurate results in as little as 15 minutes from small volume samples of many types. It has a large dynamic range and excellent sensitivity with outstanding reproducibility.