

# Genalyte Completes First Phase of National Cancer Institute Grant Program

M.D. Anderson, Providence Cancer Center and Wayne State University Install New Technology and Testing Platform for Cancer Screening

**SAN DIEGO, JANUARY 28, 2015** -San Diego based biotechnology company Genalyte announced today the completion of Phase 1 of its \$1 million National Cancer Institute (NCI) grant, successfully developing and deploying a cancer biomarker panel and testing platform for screening.

Genalyte has delivered the microchip panels and proper screening instruments to M.D. Anderson in Houston, TX; Providence Cancer Center in Providence, RI; and Wayne State University in Detroit, MI as part of a national partnership established by the NCI grant.

The test, developed by Genalyte and still in the research and discovery phase, is intended to detect antibodies arising from tumor associated antigens (TAAs) that can serve as an early warning system that the body is dealing with a cancer before the cancer can be detected as a lump or obstruction. Similar to the rapid Ebola test developed by Genalyte, the TAA test takes only 10 minutes to complete and uses one drop of serum from the blood, or a single drop of whole blood, to determine the presence of antibodies. The panel will run on Genalyte's Maverick Testing Platform, which provides rapid, accurate, detection of proteins and nucleic acids.

"The studies occurring at these three renowned cancer centers will provide insight into the ability of Genalyte's detection system to monitor how effectively a patient's own immune system is fighting their cancer," said Cary Gunn, CEO of Genalyte. "The next generation of cancer immunotherapies are targeted at harnessing the patient's own immune system to fight cancer; this program will help us understand the body's ability to fight cancer, and we are excited about the potential to play a role in this breakthrough field of medicine," Gunn added.

"We are excited about evaluating this technology, which has the potential to test multiple biomarkers from a small amount of biologic material," said Dr. Filip Janku, MD, PhD of M.D. Anderson Cancer Center.

## How the Screening Works

The analysis is conducted with a small microchip populated with sensors that can detect cancer related proteins. The test searches for antibodies in a patient's blood that bind to those proteins, and binds them to the microchip. According to clinical research, TAAs can, in some cases, recognize abnormal cell growths from cancer and trigger the body's immune system to attack the cancer cells. It is the presence of those TAAs that could allow doctors to determine if someone is showing early signs of cancer.

Genalyte's platform will allow for the one drop of serum to screen for antibodies of 32 different TAAs on one chip – making it a unique test with the ability to assess for a wide variety of cancers. Each health system involved with the program has selected a different cancer to screen. Wayne State will be focusing on breast cancer, Providence Cancer Center will study Melanoma, and M.D. Anderson will focus on advanced cancers refractory to standard therapies. By taking a broad

collection of TAAs and testing them against many types of cancers Genalyte may be able to discover patterns in people with and without the disease.

“An active immune response against a patient’s cancer can indicate which drug treatments are most likely to work for a specific patient,” said Dr. Keith Bahjat, PhD, Providence Cancer Center. “During treatment, a cancer-specific immune response can tell us that a treatment regimen is working. The Genalyte platform will allow us to perform these types of sensitive immunologic measurements rapidly and precisely, providing the opportunity for these results to inform treatment decisions.

Genalyte first garnered attention for its microchip technology and rapid, higher-accuracy testing platform in response to the global, ongoing Ebola virus crisis. Genalyte continues to partner with U.S. and international health and aid organizations to deploy its Maverick testing platform to nations combating the virus. Genalyte’s finger-prick blood test screens for as many as 15 different infectious diseases, and detects Ebola virus and other infections at the earliest symptomatic stages. Results from the screening are delivered in as little as 10 minutes.

“There have been tremendous advances in biomarker discovery in the last decade using high throughput platforms such as autoantigen microarrays to determine reactivity of large numbers of cancer and control sera, said Felix Fernandez-Madrid, professor of Internal Medicine at Wayne State University. “This project aims to validate the reactivity of autoantibodies present in breast cancer. This is done using the Maverick™ Detection System, which provides rapid, accurate, and robust detection of proteins and nucleic acids. If successful, an antibody-based non-invasive test may be able to identify breast cancer earlier, thus reducing the mortality and cost of care due to early detection of breast cancer.”

“We extend our gratitude to the National Cancer Institute for its support of this endeavor, and its commitment to research and innovation in treating and curing cancer,” said Gunn.

## 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. For more information, visit [www.genalyte.com](http://www.genalyte.com).