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Genalyte Awarded $500,000 SBIR Grant to Develop Multiplexed Assays for Early Detection and Monitoring of Type 1 Diabetes

Unique Multiplexing Capabilities of Maverick™ Detection System Could Enable Early Detection of Type 1 Diabetes and Allow for Potentially Curative Interventions

SAN DIEGO, DECEMBER 11, 2012 — Genalyte, Inc. today announced that it has been awarded a Small Business Innovation Research (SBIR) grant to develop multiplexed diagnostic assays for the early detection and monitoring of Type 1 diabetes that will run on Genalyte's innovative Maverick™ Detection System. The $500,000 grant is from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. Genalyte's novel multiplexing technology simultaneously screens for the detection of multiple autoantibodies and other proteins using a one-step, 15-minute process.

The SBIR-funded program initially will create a basic multiplexed assay to detect autoimmune response for known targets for Type 1 diabetes. It will then expand the approach to profile autoantibody response by multiple criteria, which is expected to enhance the ability of researchers and clinicians to detect and monitor the development of the disease.

> "The pioneering work of the late Dr. Eisenbarth and others established that the development of Type 1 diabetes is an incremental process, as rogue elements of the immune system over time compromise and eventually destroy the pancreatic islet cells that produce insulin," noted Martin Gleeson, PhD, Chief Scientific Officer of Genalyte. "The unique capabilities of our Maverick multiplexed detection platform have the potential to provide researchers and clinicians with the tools to detect and track this process from a very early stage, when therapeutic intervention to interrupt the process could be feasible."

Once the autoantibody panels have been developed and tested, they will be refined and validated using samples from patients with Type 1 diabetes. Genalyte expects to collaborate on this phase of the project with researchers from Dr. Eisenbarth's laboratory at the Barbara Davis Diabetes Center of the University of Colorado School of Medicine in Denver.

> Dr. Gleeson added, "From early on we envisioned that the unprecedented multiplexing capabilities of our Maverick technology would make it possible to change the way that certain diseases are diagnosed and treated. We are delighted that NIDDK is supporting development of these assays that have the potential to make this goal a reality for the millions of individuals at risk of Type 1 diabetes."

Genalyte's Maverick Detection System uses a silicon chip containing arrays of photonic ring sensors that simultaneously analyze multiple antibodies and other proteins from a single small sample. The Maverick system's one-step approach automates the washes, incubations, reagent processing and other steps needed for the analysis. Semi-quantitative results are reported for each

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analyte, eliminating the need for reflex testing. The Maverick platform has a large dynamic range and excellent sensitivity, with outstanding reproducibility.

The Maverick Detection System and its ENA 4 and ENA 6 Assay Kits are currently commercially available. They simultaneously screen for several of the most common antibodies found in autoimmune connective tissue disorders, such as lupus (SLE), Sjogren's syndrome, and scleroderma. The assay results are highly reproducible, show excellent correlation to ELISA and are up to ten times more sensitive. Assay kits for advanced SLE testing, rheumatoid arthritis and Type I diabetes are available under the Genalyte Technology Access program.

For more information about the Maverick platform and Genalyte's new Custom Chip Spotting Service, visit www.genalyte.com. Maverick assays are currently available for research use only.

About Genalyte

Founded in 2007, Genalyte, Inc. is commercializing the Maverick™ detection platform based on the company's revolutionary Microring Sensor Technology™ a new approach to multiplexing that leverages advances in silicon photonics to reduce or eliminate sample preparation, provide scalable multiplexing for both proteins and nucleic acids from a single small sample, and achieve excellent sensitivity and up to eight logs of dynamic range.

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