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Genalyte, Collaborators Gear Up for Phase Two of Tumor-associated Antigen Panel Development

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Premium

NEW YORK (GENOMEWEB) – Having completed the first phase of a $1 million National Cancer Institute grant to develop a panel of tumor-associated antibodies (TAAs) to help detect cancer and assess patient response to immune-modulating cancer drugs, Genalyte is now gearing up to manufacture a set of chips covering this panel to support the second phase of the project.

In the second phase, which ends this fall, researchers at three institutions — MD Anderson, Providence Cancer Center, and Wayne State University — will use the chips with Genalyte's Maverick Detection System to establish how the 39 TAA markers included on the panel reflect how patients respond to immunotherapy cancer drugs, or whether they are able to detect the presence of cancer early in its development.

With cancer immune response a growing area of research and numerous therapies in development aimed at using the body's own immune system to fight cancer, Genalyte CEO Cary Gunn told GenomeWeb that the company sees potential for its current research project to eventually support development of a commercial TAA chip system either for research use or inform clinical management of patients receiving these drugs.

> "It's a rapidly growing, very exciting new therapeutic area. We have to prove it, but [we believe our]technology has the potential to provide insight into how effectively the body is mounting thatimmune response," Gunn said.

Since the grant was awarded and the project began in fall of 2013, Genalyte has developed an initial panel of 39 of the most promising TAAs culled from the literature, and adapted these markers to its platform, creating the first set of chips for its collaborators to use.

> "We had a target of a fairly lengthy list of TAAs that had been characterized in the literature and we took that prioritized list and went through and evaluated to see which ones would port well onto our array system," Martin Gleeson, Genalyte's chief scientific officer said.
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> "That means getting all of these different protein types, testing a variety of different chemistries and going through a process of evaluation with control materials until we had a set we felt were robust and could be used moving forward to work with our collaborators," he explained.

Genalyte's multiplexed Maverick Detection System is based on a silicon chip containing arrays of photonic ring sensors which allows detection of proteins and antibodies from a single small sample. According to Gleeson, the group has divided the panel with about 15 markers arrayed on each chip, so for each sample the system runs three chips.

After the group's current project this arrangement could be modulated, and higher-capacity chips aresomething the company has experimented with, Gleeson said.

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In the second phase of the project, each of Genalyte's partner institutions is exploring a different cancer type. Wayne State will be focusing on breast cancer, Providence Cancer Center will study Melanoma, and MD Anderson will focus on advanced cancers that are refractory to standard therapies.

According to Gleeson, some of the samples tested in these validations will be new patient samples, while other parts of the studies will be done on archived samples. The groups are looking at hundreds of samples overall.

In addition to the main 39-marker TAA panel, one group, led by Felix Fernandez-Madrid at Wayne State University, is also looking at a select set of additional markers, Gleeson said.

Madrid's project is investigating whether the chips can be used as an early cancer detection tool using samples taken over a period of time from breast cancer patients, according to Gleeson.

> "The immune profile will be scored from pre-cancer through diagnosis and treatment. The focus is to see if we can detect at an early stage if a cancer exists, and is there a pattern that would indicate aggressive versus slower cancer types," he explained.

The other two collaborators are looking at the TAA profiles of established cancer patients, testing before and after treatment with immune-modifying drugs, he added.

Gleeson said that all three collaborators will complete their studies this fall. At that point, thecompany will have a better sense of its way forward with TAAs.

Though it does not have specific plans centered on individual therapies in development, the firm sees potential for a commercial Maverick-based TAA panel to help monitor or measure the success of therapies aimed at harnessing the body's immune system in fighting cancer.

> "The intention is that the data we generate, if we find real value we can extrapolate and use that as a tool down the road for clinicians to be able to see the response of the body against cancers," Gleeson said.

An active immune response, as measured by the presence of antibodies to relevant TAAs in a patient's blood, could indicate whether an immune-modulating drug is likely to work or currently working, and could potentially help inform better treatment decision-making.

> "This area is relatively new, but analysts are predicting $40 billion of investment into these therapeutics over the next five years," Gunn added. "If this works out as planned, [a test based on our TAA research] could be a very effective tool as these therapies are going into trials or hitting the market."

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