



BioMarker
STRATEGIES

News Release

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BioMarker Strategies Awarded Phase I National Cancer Institute Contract to Develop Novel Predictive Test for Response to Immunotherapies for Patients with Non-Small Cell Lung Cancer

Rockville, MD – September 19, 2016 – BioMarker Strategies, LLC, today announced that the National Cancer Institute (NCI) has awarded the Company a Phase I Small Business Innovation Research (SBIR) contract to develop a novel pathway-based test to predict response to immunotherapies for individual patients with non-small cell lung cancer (NSCLC).

The \$225,000 Phase I contract will support development of initial proof-of-concept data for a potential companion diagnostics test to identify patients who could otherwise be excluded from treatment with these very important therapies, because currently available tests show them as negative for the biomarkers currently used to identify patients who might benefit.

“Significant recent advances have brought forward a class of drugs known as immune checkpoint inhibitors, which enable the immune system to kill tumors,” said Jerry Parrott, President and CEO of BioMarker Strategies. “Durable responses have been observed in patients with non-small cell lung cancer who have received this treatment. Unfortunately, many patients who might ultimately respond to this important therapy may not receive it because they are considered ‘biomarker negative’ based on traditional diagnostic tests. In contrast to today’s tests, which primarily rely on dead fixed-tissue samples and static biomarkers, our SnapPath[®] Cancer Diagnostics System will use live tumor cells to enable development of a test we believe will be better able to predict an individual’s response to immune checkpoint inhibitors. This will help oncologists better tailor therapy regimes to the individual patient.”

Lung cancer is the leading cause of cancer death in the United States, with an estimated 158,040 deaths in 2015. NSCLC is responsible for 83% of these deaths.

About BioMarker Strategies

BioMarker Strategies has developed SnapPath[®], the only cancer diagnostics system that automates and standardizes functional *ex vivo* profiling of live solid tumor cells from fresh biopsies or other fresh, unfixed samples such as xenografts or tumorgrafts. SnapPath[®] can help guide cancer drug development and treatment selection. SnapPath[®] is unique in automating and standardizing functional profiling of live solid tumor cells from fresh, unfixed tissue samples – and enables the generation of PathMAP[®] Functional Signaling Profiles.

PathMAP[®] Functional Signaling Profiles represent a new class of biomarker tests, which are based on the dynamic and predictive signaling information available only from live cells. They are useful in identifying and understanding mechanisms of acquired resistance. They are highly predictive of individual tumor response to targeted therapies and combinations. BioMarker Strategies also believes that PathMAP[®] Functional Signaling Profiles will prove highly predictive of individual tumor response to immunotherapeutic approaches and combinations of immunotherapeutic approaches with targeted therapies.

The capabilities of SnapPath[®] and the Functional Signaling Profiles it enables are available for Research Use in preclinical studies in tumorgraft and other model systems, and in early clinical studies to assess pharmacodynamic changes in the solid tumors of individual patients.

In addition to the Phase I NCI contract announced today specifically for development of a novel test to predict response to immunotherapies for individual patients with NSCLC, BioMarker Strategies was recently awarded an NCI Fast Track Phase I/II grant to support development of PathMAP[®] NSCLC as a companion diagnostic test to facilitate selection of optimal therapy for patients with non-small cell lung cancer. A Phase II NCI contract is also ongoing for development of PathMAP[®] Melanoma as a companion diagnostic test to facilitate selection of optimal therapy for melanoma patients. In January 2016, BioMarker Strategies announced that patents covering our core technology have been granted in the United States, Europe, Australia and Hong Kong, and are pending elsewhere. For more information about BioMarker Strategies, please visit the company website at www.biomarkerstrategies.com.

Forward-Looking Statements

The information in this press release includes our projections and other forward-looking statements regarding future events. In some cases, forward-looking statements may be identified by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “projects,” “estimates,” “predicts,” “potential,” “continue”, etc. These statements are not guarantees of future performance or achievement and involve certain risks and uncertainties, which are difficult to predict. Therefore, actual future results and trends may differ materially from what is projected here.

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