



BioMarker
STRATEGIES

News Release

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FOR IMMEDIATE RELEASE

BioMarker Strategies Announces Phase I National Cancer Institute Grant to Develop Companion Diagnostic to Identify Patients with Head and Neck Cancer Who Are Most Likely to Respond to Treatment with Cetuximab

Rockville, MD – October 3, 2017 – BioMarker Strategies, LLC, today announced that the National Cancer Institute (NCI) has awarded the Company a Phase I Small Business Innovation Research (SBIR) grant for development of a pathway-based companion diagnostic test to identify patients with head and neck squamous cell carcinoma (HNSCC) who are most likely to respond to treatment with cetuximab. The grant will provide \$299,000 in research support.

“Cetuximab is FDA-approved for head and neck squamous cell carcinoma as monotherapy or in combination with radiation or platinum-based therapy, and it is the most widely prescribed drug for the treatment of HNSCC. Yet, the patient response rate to cetuximab based on the landmark clinical trial is only approximately 13%,” said Jerry Parrott, President and CEO of BioMarker Strategies. “There is a clear and urgent medical need for a companion diagnostic test to identify those patients with HNSCC who are most likely to respond to cetuximab.”

“We will use these funds from NCI to develop a companion diagnostic based on live HNSCC cells to provide information about response at the tumor cell signaling level to cetuximab treatment of individual head and neck squamous cell carcinomas,” Mr. Parrott said. “We believe this approach will support the optimal selection of individual patients for treatment with cetuximab alone or in combination with other therapies.”

Head and neck squamous cell carcinoma is the world’s 6th leading cause of cancer and accounts for 5% of cancer mortality. In the United States, it is estimated that the upward trend in HNSCC rates will continue in 2017, with approximately 70,000 patients newly diagnosed and approximately 14,000 deaths. Most HNSCC diagnoses occur at late stages, leading to poor prognosis and survival rates. This gives greater urgency to the need for a companion diagnostic test to improve therapeutic decision-making.

About BioMarker Strategies

BioMarker Strategies has developed the SnapPath® Cancer Diagnostics System. SnapPath is 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. The SnapPath System is an automated and highly customizable fluidics-based system

consisting of a compact bench-top instrument and a single-use cartridge for required consumables and reagents. The SnapPath system generates purified populations of live solid tumor cells from fresh unfixed tissue samples, and keeps them alive on the instrument to enable generation of highly predictive biomarker tests, which the Company has named PathMAP® Functional Signaling Profiles.

PathMAP Functional Signaling Profiles, such as the companion diagnostic for cetuximab that BioMarker Strategies plans to develop under the current NCI Phase I grant, 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, and 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.

The SnapPath and PathMAP technologies are ideally suited to assess response to targeted drugs in development for the treatment of patients with solid tumor cancers, in preclinical studies in xenograft, tumorgraft and other model systems, and in early clinical studies to assess pharmacodynamic changes in the solid tumors of individual patients. The BioMarker Strategies business model is focused on using the Company's proprietary *ex vivo* technology to provide research services to companies developing these treatments.

Patents covering the SnapPath Cancer Diagnostics System have been granted in the United States, Europe, Australia, Hong Kong, Japan and Korea. A patent has also been officially allowed and is proceeding to grant in Canada.

Patents covering the PathMAP Functional Signaling Profile technology have now been granted in the United States, Europe, Australia, Japan and Singapore, and patent applications are pending elsewhere.

For more information about BioMarker Strategies, please see 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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