



## PRESS RELEASE

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### **NUCLEA DISCOVERY COULD SIGNIFICANTLY IMPROVE PROSTATE CANCER DIAGNOSIS, TREATMENT**

*Fatty Acid Synthase found to be better predictor than PSA*

Pittsfield – Worcester, MA -- Biomarker pioneer Nuclea Biotechnologies, Inc. today released new research that could significantly alter and improve the way prostate cancer is diagnosed and treated. Nuclea filed a patent application this week after research conducted by the company in conjunction with research performed by Dr. Massimo Loda at the Dana Farber Cancer Institute found a predictive relationship between Fatty Acid Synthase (FAS) and degree of regression and clinical survival in patients with prostate cancer.

“This could be a game-changer for men who are at high-risk of metastasis from prostate cancer,” said Patrick J. Muraca, president & CEO of Nuclea. “Too many men are being misclassified and ineffectually treated. Using this assay, doctors will be able to correctly classify and diagnose 95% of patients suffering from this deadly disease – more than a 20% increase over current diagnostic tools.”

According to the American Cancer Society, there were more than 217,000 cases of prostate cancer reported in the United States in 2010, and more 32,000 related deaths. Currently, the most widely used detection tool is an assay that measures the levels of the biomarker PSA, or prostate specific antigen. But according to the National Cancer Institute, PSA levels alone do not give doctors enough information to distinguish between benign prostate conditions and cancer. As men age, both benign prostate conditions and prostate cancer become more common, resulting in an increase in PSA levels. As a result, PSA assays are believed to correctly diagnose prostate cancer only in about 75% of patients.

Nuclea has been working to find a better solution. For the past three years, Nuclea has sponsored FAS research projects in the laboratory of Dr. Massimo Loda at the Dana Farber Cancer Institute. Working with Dr. Loda, Nuclea engaged in a clinical trial to determine the clinical and prognostic significance of FAS and another prostate cancer biomarker, USP2A, for determining the aggressiveness of prostate cancer. Following successful initial results, Nuclea, working with Dana Farber, will launch a large clinical study to expand on the research. Dr. Loda and his colleagues have published numerous peer-reviewed articles showing the diagnostic and prognostic significance of FAS. Nuclea will publish the company’s new research shortly.

“Fatty Acid Synthase, the principal enzyme for the synthesis of lipids essential for tumor growth, is significantly upregulated in most cancers, including prostate cancer,” said Dr. Loda. “In prostate cancer, its presence and high expression is associated with the development of metastases and aggressive disease, particularly in overweight men.”

“We believe that this new FAS assay will eventually replace PSA and Gleason as the most reliable method of diagnosing the severity of prostate cancer,” added Muraca. “What’s more, by looking at FAS and the biomarker USP2A, we will be able to more accurately predict a patient’s prognosis and treat them accordingly.”

The company’s research concluded, and confirmed by Dr. Loda’s team, that USP2A and FAS create a pattern of expression that “provides a highly significant and powerful means of predicting cancer aggressiveness in the context of degree of regression,” or the speed at which cancer negatively impacts a patient. Nuclea believes that, by providing a better understanding of aggressiveness, they can help doctors and patients quickly identify the most effective treatment options.

**Nuclea Biotechnologies, Inc.** is headquartered in Pittsfield, Massachusetts with additional operations in Worcester, Massachusetts. Nuclea has developed and is commercializing eleven unique diagnostic tests for colon, breast, leukemia, lung and prostate cancer. Nuclea also performs research leading to novel molecular oncology therapeutics and diagnostics for the pharmaceutical and biotechnology industries.