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Caris Life Sciences’ Non-Invasive Liquid Biopsy Platform ADAPT Biotargeting System Demonstrates Potential to Improve Accuracy of Breast Cancer Diagnosis

SABCS Late-breaking Study Shows ADAPT Biotargeting System May be an Effective Diagnostic Adjunct to Routine Mammography for Women with Dense Breast Tissue

Irving, TX, Dec. 10, 2015 – Caris Life Sciences® presented results from the first study using its revolutionary technology called ADAPT (Adaptive Dynamic Artificial Poly-ligand Targeting) Biotartgetting System™ to perform multiplexed biomarker discovery in human plasma. The study shows blood plasma contains circulating complexes which contain information that could serve as a diagnostic adjunct to mammography for women with dense breast tissue. In a late-breaking poster presentation at the 2015 San Antonio Breast Cancer Symposium (SABCS), researchers reported results of experiments indicating that ADAPT is equally effective in difficult cases for which imaging technologies are insufficient for characterizing breast tissue as cancerous or non-cancerous.

“There is a significant need to improve screening methods in women with dense breast tissue as standard mammography often fails to provide accurate information about the nature of breast tissue abnormalities, which often leads to unnecessary anxiety, cost and possible morbidity from additional imaging and biopsies,” commented David Spetzler Ph.D., Chief Scientific Officer at Caris Life Sciences. “ADAPT is a non-invasive liquid biopsy method of profiling plasma exosomes, which are small lipid vesicles secreted by many types of cells, to determine if they were derived from tumor cells or healthy cells. This proof-of-concept study shows that ADAPT may be a powerful diagnostic adjunct to mammography, and a potentially important breast cancer screening tool for women with dense breast tissue.”

The ADAPT platform was built upon a large library of approximately $10^{15}$ oligonucleotides engineered to adopt a highly complex set of unique three-dimensional binding sites. In the study, investigators incubated the ADAPT library with plasma samples from 60 breast cancer patients and from a control cohort of 60 healthy women. Differentially bound (cancer vs. non-cancer) oligonucleotides were recovered from precipitated exosomes and identified via Next-Generation Sequencing. Two thousand oligonucleotides were selected, resynthesized and used to probe a broader set of 500 plasma samples from a cohort of breast cancer patients (n=206) and a control cohort comprising self-reported healthy volunteers (n=117) and patients whose biopsies led to a diagnosis of non-cancer (n=177).

The researchers employed several statistical models to build a cancer/non-cancer classifier, including a random forest model (RFM), which yielded a classification performance with areas under the receiver-operator characteristic curve (ROC AUC) of 0.66, indicating that the 2,000 selected oligonucleotides contained biologically important information. Several statistical approaches were employed to assess and reduce the risk of false discovery. Importantly, incorporation of BIRAD (Breast Imaging-Reporting and
Data), a widely used risk assessment and quality assurance tool in mammography, ultrasound or magnetic resonance imaging (MRI) results as a clinical covariate did not influence model performance, indicating that classifications made by ADAPT were independent of breast tissue density.

“While we are greatly encouraged by the results obtained thus far, we are committed to improving the performance of the ADAPT platform through further optimization of the aptamer library and testing on additional samples,” said David D. Halbert, Chairman and CEO of Caris Life Sciences. “Upon complete validation, an ADAPT-derived breast cancer test will serve as a vital diagnostic adjunct that can be easily incorporated into standard clinical practice. ADAPT is also likely to prove useful in other tumor types and disease areas, since it provides the capability to identify a wide range of biomarkers with diagnostic applications from small volume plasma samples.”

About Caris Life Sciences®
Founded by David D. Halbert in 2008, Caris Life Sciences® is a leading biotechnology company focused on fulfilling the promise of precision medicine through quality and innovation. Caris Molecular Intelligence®, the company’s healthcare information and comprehensive tumor profiling service with more than 80,000 patients profiled, provides oncologists with the most clinically actionable treatment options available to personalize cancer care today. Using a variety of advanced profiling technologies to assess relevant biological changes in each patient’s tumor, Caris Molecular Intelligence connects biomarker data generated from a tumor with biomarker-drug associations supported by evidence in the relevant clinical literature. Since 2009, Caris Life Sciences has tracked clinical and outcome data for certain patients undergoing tumor profiling, and has observed that patients treated with drugs consistent with their tumor profile show a significant increase in overall survival. The company is also developing its ADAPT Biotargeting System™, a revolutionary and unbiased profiling platform with applications across therapy development, drug delivery, advanced diagnostics and disease monitoring. Currently being developed for cancer and other complex diseases, the ADAPT Biotargeting System is able to simultaneously measure millions of molecular interactions within complex biological systems in their natural state(s). Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Australia and other international markets. To learn more, please visit www.CarisLifeSciences.com.

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