

MetaStat Presents Positive Data from Two Clinical Studies of MetaSite Breast™ at 2016 San Antonio Breast Cancer Symposium

MetaSite Breast™ a novel automated breast cancer test, predicts the development of distant cancer metastasis in Hormone Receptor-Positive HER2-Negative Early Stage

Breast Cancer

The assay provides complimentary prognostic information to Genomic Health's Oncotype DX gene panel to further guide treatment decisions for Patients with low Recurrence Scores

Patients in a recent clinical study with low Oncotype DX Recurrence Score results but high MetaSite Breast™ Score, had a ~10x higher risk of forming distant metastasis, than patients in the same group with low MetaSite Breast™ Scores

BOSTON--(BUSINESS WIRE)-- **MetaStat, Inc. (OTCQB:MTST)**, a pre-commercial biotechnology company, today announced results from two clinical studies of its MetaSite *Breast*™ test reported at the 39th San Antonio Breast Cancer Symposium (SABCS) demonstrating that the MetaSite Score was significantly associated with increased risk of distant metastasis in Hormone Receptor (HR-positive), HER2-negative Early Stage Breast Cancer (ESBC). Data include results from the Kaiser Permanente Cohort Case-Control Study and the ECOG2197 Clinical Trail Cohort Study led by the ECOG-ACRIN Cancer Research Group. "We are pleased to present positive results from two prospectively designed, retrospective studies of MetaSite *Breast*™ confirming the clinical validity of the association between MetaSite Score and distant cancer metastasis," said Douglas A. Hamilton, MetaStat's President and Chief Executive Officer. "Data generated from these studies demonstrate that our MetaSite *Breast*™ test offers the potential to more accurately guide treatment decisions when added to the most widely utilized gene expression assay, Oncotype DX."

"These results further support the importance of incorporating intact tissue-based analyses when generating prognostic risk models. The ability to visualize and quantify biological attributes in tissue sections will continue to advance the field of precision medicine," added Michael J. Donovan, PhD, MD, MetaStat's acting Chief Medical Officer.

Results from the Kaiser Permanente Cohort Study conducted by MetaStat, demonstrated MetaSite Score was a statically significant predictor of distant metastasis and a binary cutpoint was able to discriminate high and low risk patient groups when adjusted for clinical factors. Dr. Joseph Sparano, principal investigator for MetaStat's ECOG2197

Cohort Study, presented data demonstrating the MetaSite *Breast*[™] test is prognostic for distant metastatic recurrence within 5 years and provides complementary prognostic and potentially clinically actionable information to the low/mid-range Recurrence Score from Genomic Health's (NASDAQ:GHDX) Oncotype DX, breast cancer test.

Independent verification and clinical validation of MetaStat's fully automated and analytically validated tissue-based MetaSite Breast™ test for risk of cancer metastasis in HR-positive HER2-negative ESBC.

The Kaiser Permanente Cohort Prognostic Study is a case-control nested cohort of 3,760 patients diagnosed with ESBC from the Kaiser Permanente Northwest Health Care System in which 464 tumor samples were tested using the MetaSite *Breast*™ assay. MetaSite Score was a statistically significant predictor of distant metastasis (p=0.039) in patients with HR-positive HER2-negative disease. Using predefined cutpoints based on tertiles for the control group in the overall study population (n=282), MetaSite Score was significantly associated with distant metastasis for the high (MS>41) versus low (MS<13) score tertiles (OR=2.94; 9%Cl=1.62-5.41, p=0.0005) and the intermediate (MS=13-41) versus low score tertiles (OR=2.24; 95%Cl=1.23-4.13, p=0.009). A binary cut-point for the high risk group (MS>14) was significant with a 2-fold higher risk (OR=2.1, 95%Cl=1.06-3.96) of distant metastasis versus the low risk group and adjusted for clinical covariates (p=0.036).

A second study of the MetaSite Breast™ test in a uniformly treated clinical trial cohort confirmed the clinical validity of the association between MetaSite Score and distant recurrence in patients with HR-positive HER2-negative ESBC.

The ECOG2197 Cohort Prognostic Study is a prospectively designed retrospective study (n=600) in an independent cohort (E2197; NCT00003519) of ESBC patients treated with surgery, 4 cycles of adjuvant chemotherapy (doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2 (AC) or docetaxel 60 mg/m2 (AT)) and endocrine therapy. Results from this study revealed a significant positive association between continuous MetaSite Score and distant recurrence-free interval (DRFI) p=0.001 and recurrence-free interval (RFI) p=0.00006 in HR-positive HER2-negative disease in years 0-5 and by MetaSite Score tertiles for DRFI (p=0.04) and RFI (p=0.01). Proportional hazards models including clinical covariates (N0 vs. N1; T1 vs. T2; high vs. int. vs. low grade) also revealed significant positive associations for continuous MetaSite Score with RFI (p=0.04), and borderline association with DRFI (p=0.08).

MetaSite Breast™ provides useful prognostic information beyond the Genomic Health's Oncotype DX Recurrence Score. Patients with high and intermediate MetaSite Score (MS>6) and low Recurrence Score (RS<18) results had 5 to 10-fold greater risk of distant recurrence compared to low MetaSite Scores (MS<6).

Patients with high MetaSite Score (MS>17) and low Recurrence Score (RS<18) results had 9.7-fold greater risk (HR=9.7, 95%Cl 1.8-54.1) of distant metastasis compared to patients with low MetaSite Score (MS<6) results. Patients with intermediate MetaSite Score (MS=6-17) and low Recurrence Score (RS<18) results had approximately 4.7-fold greater risk (HR=4.7, 95%Cl=0.9-24.2) of distant metastasis compared to patients with low MetaSite Score (MS<6) results.

About MetaSite Breast™

The MetaSite *Breast*[™] test is intended for use in patients with early stage (stage 1-3), invasive breast cancer who have node-negative or node positive, Hormone Receptor (HR)-positive, HER2-negative disease. Clinical studies have demonstrated the MetaSite score (MS) is significantly associated with increased risk of cancer metastasis. MetaSite *Breast*[™] is an analytically validated, fully automated digital pathology/image analysis assay that identifies Mena expressing tumor cells in direct contact with CD68+ perivascular macrophages and CD31+ endothelial cells ("MetaSites"). MetaSites have been shown to be the portal of entry for cancer cells into the blood stream contributing to the development of cancer metastasis. The MetaSite *Breast*[™] assay is performed on standard formalin-fixed paraffin-embedded (FFPE) tissue, analytically validated under CLIA and clinically available through MetaStat's CLIA-certified commercial laboratory located in Boston, MA.

About MetaStat, Inc.

MetaStat, Inc. (MTST) is a pre-commercial biotechnology company focused on the development and commercialization of diagnostic tests that are prognostic for the risk of cancer metastasis, companion diagnostics to predict drug response, and anti-metastatic drugs. Our driver-based platform technology is based on the pivotal role of the Mena protein and its isoforms, a common pathway for the development of metastatic disease and drug resistance in epithelial-based solid tumors.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are cautioned that such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events or results to differ materially from those projected in the forward-looking statements as a result of various factors and other risks, including those set forth in the company's Form 10-K filed with the Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included herein, and not place undue reliance on such statements. The forward-looking statements in this release are made as of the date hereof and the company undertakes no obligation to update such statements.

View source version on businesswire.com: http://www.businesswire.com/news/home/20161213005457/en/

Investors:
MetaStat, Inc.
Rick Pierce, 617-531-0874
Rpierce@metastat.com

Source: MetaStat, Inc.