MetaStat Presents Positive Analytical Validation Data for MetaSite Breast™ Cancer Diagnostic Test

Data presented today at the American Association for Cancer Research Supports the Accuracy, Reproducibility, and Precision of the MetaSite Breast™ Test

BOSTON-- MetaStat, Inc. (OTCQB:MTST), a molecular diagnostic company, today presented positive results from an analytical validation study demonstrating the analytical accuracy, reproducibility, and precision of its MetaSite Breast™ test at the Tumor Metastasis meeting of the American Association for Cancer Research (AACR) in Austin, Texas.

The MetaSite Breast™ test predicts the likelihood of distant cancer metastasis in patients with early-stage ER-positive invasive breast cancer and allows physicians to both optimize treatment decisions and ultimately improve patient outcomes. The test identifies and measures the number of micro-anatomical structures (MetaSites) consisting of a Mena protein expressing tumor cell, an endothelial cell, and a perivascular macrophage, all in direct contact. MetaSites are hypothesized to be the portal of entry for cancer cells into the blood stream contributing to the development of metastasis.

“Quantitative variability and agreement is a well-known issue among pathologists,” said Douglas A. Hamilton, President and Chief Executive Officer of MetaStat. “MetaStat leverages advances in automated digital pathology, image analysis, and customized algorithms to set a higher standard of analytical accuracy and reproducibility as evidenced by the data presented today at AACR.”

In this study, MetaStat assessed the analytical precision and accuracy of the fully-automated clinical MetaSite Breast™ test using formalin-fixed, paraffin-embedded (FFPE) tissue samples from patients with invasive breast cancer. MetaSite Breast™ was shown to have analytical precision of greater than 97% with a mean percent coefficient of variation (%CV) of 6.6% (n=35). Pathologist quality review showed a high degree of precision between two pathologists by ROC analysis with AUCs (area-under-the-curve) ranging from 0.97 to 1.0 over three independent sample set reviews (n=105). Additionally, overall assay performance using different instruments, operators and tumor sections performed over three consecutive days was highly reproducible with AUCs for MetaSite score classification ranging from 0.91 to 0.96. Importantly, MetaSite Breast™ showed a high degree of analytical accuracy with the reference standard (semi-manual pathologist MetaSite/TMEM counting) by ROC analysis with AUCs of 0.84 and 0.90 for low and high risk cut-points, respectively. The reference standard method was originally developed at the Albert Einstein College of Medicine where they have previously demonstrated the number of MetaSites/TMEMs in tumors to be predictive of distant metastatic disease in
ER-positive breast cancer patients (Rohan et al. JNCI 2014).

The study was presented as a poster entitled “Development and analytical validation of a fully-automated platform for quantification of MetaSites to predict systemic metastasis”. (Abstract #B64)

About MetaStat, Inc.

MetaStat, Inc. (MTST) develops and commercializes tissue-based diagnostic tests for prediction of cancer metastasis. MetaStat is focused on breast, lung, colorectal and prostate cancers, where aggressive cancer is responsible for approximately 90% of all deaths. MetaStat's 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 in all epithelial-based solid tumors. Both the MetaSite Breast™ and MenaCalc™ assays are designed to accurately stratify patients based on the aggressiveness of their tumor and risk the cancer will spread. MetaStat's testing platform improves treatment planning decisions by positively identifying patients at high-risk of metastasis who need aggressive therapy and by sparing patients with a low-risk of metastasis from the harmful side effects and expense of chemotherapy.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning 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 and other filings made 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.


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