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MONITORING CIRCULATING TUMOR CELLS WITH THE CELLSEARCH® SYSTEM CAN PREDICT PROGNOSIS IN METASTATIC BREAST CANCER

New Study Reinforces Important Role of Integrating Therapeutic Monitoring Tools

RARITAN, N.J., (July 13, 2009) – Measuring the change in circulating tumor cell (CTC) count can accurately predict the prognosis and survival in patients with metastatic breast cancer (MBC), according to a newly published report in the July 10 issue of the *Journal of Clinical Oncology*. The retrospective study compared how well CTCs and a more sensitive than conventional modality, fluorodeoxyglucose positron emission tomography/computed tomography (FDG-PET/CT), predicted survival in MBC patients on standard therapies. The comparison showed that both technologies significantly correlate to overall MBC patient survival ($p<0.001$ for CTCs and $p=0.001$ for FDG-PET/CT). However, a CTC count of five or more could better predict the prognosis and survival in MBC patients.

The CellSearch® System is the first 510(k) diagnostic test used to automate the capture and detection of CTCs, tumor cells that have detached from solid tumors and entered the patient's blood.

"Measuring CTCs in metastatic breast cancer patients provides oncologists with an additional tool to help us better monitor patient outcomes," said one of the lead authors, Dr. Massimo Cristofanilli*, associate professor in the Department of Breast Medical Oncology at The University of Texas M. D. Anderson Cancer Center. "The CellSearch®

CTC test provides an early indication about patients' disease progression and overall survival."

CTCs and FDG-PET/CT are two of the most promising new tools for therapeutic monitoring in patients with MBC. The number of CTCs identified in patients with MBC is related to patient prognosis; a high number of CTCs at any time during treatment is associated with poor prognosis.

"Veridex is committed to providing oncologists with high-value *in vitro* diagnostic solutions, such as the CellSearch® CTC test, to help them make informed patient care decisions," said Ken Berlin, general manager of Veridex. "This study demonstrates the utility of integrating the CellSearch® CTC test in therapeutic monitoring of patients with metastatic disease."

Study Design

A retrospective study was performed on 115 patients with MBC who had the CellSearch test performed as part of their initial staging process at M.D. Anderson over a three-year period. CTC count and FDG-PET/CT imaging were performed at baseline in 102 evaluable patients before starting a new therapy and then again at the midpoint of their therapies (9 - 12 weeks). Patients outcomes were categorized according to midtherapy CTC counts as favorable (< five CTCs/7.5 mL blood) or unfavorable (≥ five CTCs/7.5 mL blood). Based on FDG-PET/CT, patients were considered responders if metabolic activity of target lesions decreased more than 25% compared to baseline, and if there was no change or a decrease in size. Patients were considered nonresponders if the FDG uptake was similar or higher and/or if target lesions had increased in size. CTC counts and FDG-PET/CT response at midtherapy were compared, and univariate and multivariate analyses were performed to identify factors associated with survival.

Study Findings

A total of 115 patients with MBC were considered for the study and 102 were evaluable for efficacy. The median overall survival time was 14 months (range, 1 to > 41 months). In univariate analysis, both midtherapy CTC counts and FDG-PET/CT response predicted overall patient survival ($p<.001$ and $p=.001$, respectively). The overall concordance between the CTC counts at midtherapy and FDG-PET/CT was 67% for response/nonresponse and 74% for progression/nonprogression. In the discordant category, detection of five or more CTCs during therapeutic monitoring accurately

predicted prognosis in MBC beyond metabolic response. FDG-PET/CT was able to predict outcome in discordant instances of patients with less than five CTCs at midtherapy. Midtherapy CTC levels remained significant in a multivariate analysis (p=.004). These results suggest a higher and independent predictive value of CTCs compared with FDG-PET/CT among patients with a CTC count of five or more. In addition, there was a strong correlation between complete response and the absence of significant levels of CTCs (median CTC level zero).

* Dr. Cristofanilli is a principal investigator for a CellSearch® validation study and received honoraria from Veridex, LLC.

About CellSearch®

The CellSearch® test works by using antibodies that are joined to microscopic iron particles, called ferrofluid. These antibody/ferrofluid combinations attach very specifically to CTCs. Powerful magnets then draw the CTCs out of the blood sample and they are then stained with additional bio-molecules and chemicals so that they can be positively identified as CTCs.

CellSearch® test results should be used in conjunction with all clinical information derived from diagnostic tests (e.g., imaging, laboratory tests), physical examination and complete medical history in accordance with appropriate patient management procedures. For further information on intended use, warnings and limitations, please refer to the CellSearch® CTC Test Instructions for Use, or visit www.veridex.com.

About Veridex, LLC

Veridex, LLC, a Johnson & Johnson company, is an organization dedicated to providing physicians with high-value *in vitro* diagnostic oncology products. Veridex's products may significantly benefit patients through earlier disease detection and may enable personalized strategies to help improve patient management and outcomes. For more information, visit www.veridex.com.

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