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Biovica's DiviTum Test Speeds-Up Breast Cancer Diagnosis In Study

by [Reed Miller](#)

Results from a Swedish study that will be presented at the San Antonio Breast Cancer Symposium in December show that Biovica's *DiviTum* blood-based biomarker test provides a valuable marker for accurate prognosis of metastatic breast cancer therapy after just one month.

Biovica International AB's non-invasive *DiviTum* blood-test accurately predicts the progression-free and overall survival prognosis for patients undergoing treatment for metastatic breast cancer just one month into treatment, according to the results of the [CTC-MBC](#) study announced Nov. 14.

By dramatically shortening the "evaluation window," DiviTum can help physicians and patients make decisions to continue or change treatment at a point in the disease progression where these decisions can lead to better patient outcomes, according to the Swedish company.

Results of the study, led by Anna-Maria Larsson of Lund University in Sweden, will be presented on Dec. 7 at the San Antonio Breast Cancer Symposium, but Biovica announced them early and an [abstract](#) of the study is posted online.

Larsson and colleagues explain that more precise prognoses and treatment-monitoring could improve outcomes in metastatic breast cancer patients and that liquid biopsy tests, which identify biomarkers in fluids such as blood, are the most promising technology for this application because they can show the real-time tumor progression without invasive tissue-biopsies.

Thymidine kinase 1 (TK1), an enzyme involved in nucleotide metabolism and DNA synthesis, is a marker of cell proliferation rate that correlates to the prognosis and usefulness of treatment monitoring in different malignancies, the authors explain.

The study enrolled 142 women with metastatic breast cancer scheduled for first-line systemic treatment and tested their blood with DiviTum to determine serum TK1 activity (sTK1) levels in patients scheduled for the first-line systemic therapy and test its ability to predict outcomes and monitor treatment. All of the patients were evaluated for sTK1 at baseline and during treatment at one, three, and six months; ten patients dropped out. The sTK1 activity levels were correlated to important progression-free survival and overall survival.

The median baseline sTK1 level was 391 u/L and sTK1 levels above the median were associated with a worse performance status and a high number of metastatic sites compared to patients with levels below the median. Also, high sTK1 levels were associated with greater expression of the Ki-67 protein, a cellular marker of proliferation, in biopsies from metastatic lesions.

A univariable analyses showed sTK1 was an independent prognostic factor for both progression-free survival and overall survival. During treatment, sTK1 was significantly associated with overall survival at each of the four time points and onwards. High sTK1 levels were also associated with significant impairment in progression-free survival and these associations were significant at baseline and six months.

"These results are clinically relevant for prognostication and treatment monitoring in patients with metastatic breast cancer," Larsson et al. conclude. "Future studies of sTK1 are justified to further elucidate in what settings this marker is most useful."

"The study provides key documentation for DiviTum as a tool for putative evaluation of efficacy in a peripheral blood sample and we are delighted to publish these results in collaboration with Lund University," Biovica CEO Anders Rylander said. "The study results contribute towards our objective of supplying DiviTum to oncologists as a standard tool for evaluating metastatic breast cancer treatment to improve patient outcome."

Biovica was founded in 2009 to develop and commercialize blood-based biomarker assays to monitor cancer therapies and better predict patient outcomes. The company is initially focused on applying the DiviTum technology to breast cancer. Biovica's clinical validation plan is supported by the European Commission and partly funded by the EC's [Horizon 2020 program](#). Biovica's shares are traded on NASDAQ First North in Stockholm as BIOVIC B.

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