PRESS RELEASE
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Newly published data reinforce robust prognostic associations for DiviTum® TKa in metastatic breast cancer

Biovica, a leader in blood-based cancer monitoring, today announces that results from the prospective PDM-MBC (Personalised Disease Monitoring in Metastatic Breast Cancer) study have been published in Breast Cancer Research and Treatment. The results show that DiviTum® TKa provides robust prognostic information on both progression-free and overall survival across several early time points. The findings also indicate that thymidine kinase 1 activity (TKa) acts as a continuous marker of risk, supporting more refined modelling approaches for personalized monitoring assessment.

The study evaluated TKa, measured with the DiviTum TKa assay, in 90 patients with HR+/HER2- metastatic breast cancer receiving first-line CDK4/6 inhibitor plus aromatase inhibitor therapy. Baseline sampling offered practical and reliable prognostic value, while early on-treatment changes added additional insight in patients with high baseline TKa.

"Our results add to the existing evidence that thymidine kinase 1 activity (TKa), measured using the DiviTum® assay, provides prognostic information on progression free and overall survival in HR+/HER2– metastatic breast cancer treated with first line CDK4/6 inhibitor plus aromatase inhibitor therapy. A key contribution of this study is the systematic evaluation of TKa across multiple early time points and thresholds, demonstrating consistent prognostic associations. Baseline testing is clinically practical for initial risk assessment, while early on-treatment changes in TKa may offer additional prognostic insight in patients with high baseline levels. In addition, the findings highlight that TKa behaves as a continuous marker of risk, suggesting that continuous modelling could provide more nuanced individual risk information to support the development of personalized monitoring and follow-up frameworks, while thresholds may retain value in specific clinical contexts. These findings support further evaluation of DiviTum TKa within personalized risk assessment frameworks, pending validation in larger prospective studies," said principal investigator and Associate Professor Maria Ekholm, MD, PhD.

The PDM-MBC study followed patients closely with predefined blood sampling and imaging intervals reflective of routine clinical practice. While the study was designed to evaluate longitudinal biomarker monitoring in relation to imaging needs, the present analysis includes samples collected during the first four weeks of treatment. Importantly, these findings support the role of TKa as a continuous marker of risk, providing a scientific rationale for further development of refined prognostic modelling approaches and biomarker-informed follow-up strategies to be prospectively evaluated in clinical trials.

"The study strengthens the clinical evidence for DiviTum® TKa as a tool for ongoing risk assessment in metastatic breast cancer. By enabling more precise patient stratification, the findings support a more tailored approach to monitoring, with potential benefits for both patients and healthcare systems," said Anders Rylander, CEO of Biovica.

The publication represents an additional milestone in Biovica's efforts to expand the clinical evidence base for DiviTum TKa and its potential role in personalized monitoring strategies for metastatic breast cancer. Following peer review, the study was published in Breast Cancer Research and Treatment, a leading international journal in breast cancer research.

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Biovica – Treatment decisions with greater confidence

Biovica develops and commercializes blood-based biomarker assays that help oncologists monitor cancer progression. Biovica's assay, DiviTum® TKa, measures cell proliferation by detecting the TKa biomarker in the bloodstream. The assay has demonstrated its ability to provide insight to therapy effectiveness in several clinical trials. The first application for the DiviTum® TKa test is treatment monitoring of patients with metastatic breast cancer. Biovica's vision is: "Improved care for cancer patients." Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum® TKa has received FDA 510(k) clearance in the US and is CE-marked in the EU. Biovica's shares are traded on the Nasdaq First North Premier Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser. For more information, please visit: www.biovica.com

Attachments

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