PRESS RELEASE
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New phase III translational data show DiviTum® TKa captures treatment-specific biological response in metastatic breast cancer

Biovica, specializing in blood-based cancer monitoring, today announced new data published in the European Journal of Cancer showing that DiviTumTKa can capture early, treatment-specific biological response in patients with endocrine-resistant HR+/HER2– metastatic breast cancer.

The analysis included 555 patients from the phase III GEICAM/2013-02 PEARL trial and used Biovica's FDA 510(k)-cleared DiviTum TKa assay. Patients were randomized to receive either targeted therapy (ET + palbociclib) or chemotherapy (capecitabine).

The key new insight is that TKa did not behave the same way across treatments. Instead, early TKa changes reflected how each therapy affected tumor biology — increasing in patients who benefited from capecitabine, an oral chemotherapy, while confirming previous findings that effective CDK4/6-based treatment is associated with early TKa suppression.

The authors also highlight that TKa provides unique information that may complement ctDNA. While ctDNA provides important genomic information about tumor mutations and clonal evolution, TKa provides a functional, real-time readout of tumor proliferation and biological treatment activity. In simple terms, ctDNA can help show what genetic changes are present, while TKa can help show what the cancer is doing during treatment.

"This analysis is part of GEICAM's commitment to advancing translational research with a real impact on clinical practice. TKa is a robust blood-based marker that makes it possible to monitor tumor activity in real time. Our study shows that its early changes, just 15 days after treatment begins, very clearly predict which patients are responding. It is a tool that can help us better understand treatment response and move toward increasingly personalized care in metastatic breast cancer," says Dr. Ángel Guerrero Zotano, one of the researchers involved in this study and member of GEICAM' s Board of Directors.

" What makes these findings particularly compelling is that TKa doesn't just confirm response — it differentiates it. The marker behaves distinctly depending on how a therapy works biologically, which means clinicians get a real-time functional signal that genomic tools simply cannot provide. As oncology accelerates toward truly personalized treatment, we believe DiviTum TKa is becoming an essential part of that picture — and data of this quality, at this scale, strengthens our confidence in the path ahead," says Theis Kipling, CEO of Biovica.

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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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