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PRESS RELEASE
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DiviTum® TKa clinical validation data published in Biomarkers

Biovica, active in cancer diagnostics, today announces that results clinically validating the DiviTum® TKa assay have been published in the scientific journal Biomarkers. The results, from an analysis of samples and clinical data from the SWOG S0226 study, support the use of DiviTum® TKa when monitoring metastatic breast cancer patients and were the foundation leading to FDA clearance of the assay.

"The analysis of samples and data from SWOG S0226, provided the clinical validation data that resulted in 510(k) clearance of DivTum® TKa from the FDA. The fact that this work now has also been accepted and published in a scientific journal enables Biovica to use these strong data as an asset when promoting DiviTum® TKa to customers. DiviTum® TKa is a tool for effective monitoring of treatments within metastatic breast cancer, something that will benefit both patients and health care providers," said Anders Rylander, CEO of Biovica.

Among the patient samples tested, DiviTum® TKa test values below the pre-specified cut-off, both before and during treatment, predicted low likelihood of disease progression – the so-called Negative Predictive Value (NPV) - with very high accuracy and precision. The DiviTum® TKa test's NPVs for disease progression within 30 and 60 days after TKa testing were 96.7% and 93.5%, respectively. This means that 96.7% of patients with DiviTum® TKa measurements below the assay clinical cut-off did not experience disease progression within the next 30 days. A high NPV reveals that it is unlikely for a woman to progress in the disease, indicating that the current treatment is effective.

Further, a low TKa value at first follow up (approx. 8 weeks into treatment) indicated longer time to progression vs. high TKa values; 17.5 vs 7.7 months with corresponding numbers for overall survival being 56.6 vs 27.4 months.

Investigators conclude that low serum DiviTum® TKa levels can identify patients who will do well for a long time as well as patients who might forego additional therapy added to standard, single-agent endocrine therapy. The combined effect of avoiding ancillary treatments with a possible reduction of inconvenient and costly serial imaging, should improve the quality of life for patients.

Link to study: https://www.tandfonline.com/doi/full/10.1080/1354750X.2023.2168063

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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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