PRESS RELEASE
August 24, 2023

Biovica announces the start of a DiviTum® TKa clinical trial

Biovica, active in cancer diagnostics, today announces the initiation of a prospective clinical trial to study the correlation between DiviTum TKa levels and the effects of medication dose reductions in the care of metastatic breast cancer patients.

"We are very proud to be partnering with Yale on such an important prospective study. If successful, the trial strengthens DiviTum TKa's clinal evidence which is very valuable in relation to guidelines and reimbursement. Ultimately, the correlation between DiviTum TKa, improved CDK4/6i response and better outcomes is what Biovica is striving for on behalf of patients," said Anders Rylander, CEO of Biovica.

The study aims to correlate thymidine kinase activity (TKa) levels, as measured by DiviTum TKa, with medication non-compliance, potential drug-drug interaction issues, and the effects of medication dose reductions in ER/PR-positive HER2-negative metastatic breast cancer patients receiving first-line therapy with a CDK4/6 inhibitor in combination with endocrine therapy. The study's Principal Investigators are Mariya Rozenblit, MD, Assistant Professor of Medicine (Medical Oncology) and Lajos Pusztai, MD, PhD, Professor of Medicine (Medical Oncology), at Yale School of Medicine and Yale Cancer Center.

Taking more than one medication at a time, is very common in patients with cancer and can lead to poor treatment effectiveness by reducing treatment drug concentration levels. Drug dose reductions of CDK4/6 inhibitors to manage side effects are also common and may impact the efficacy of the drug in some patients. Circulating TKa has previously been identified in several studies as a predictor of therapy efficacy in metastatic breast cancer.

The study will use DiviTum TKa to measure TKa in "real time" from patient serum samples obtained during routine monitoring blood draws. All patients will be assessed for medication compliance, potential drug-drug interaction issues, and dose reductions. Counseling and optimization of concurrent medications will be conducted if an issue is identified. Changes in TKa levels will be analyzed for correlation with improved CDK4/6i response, duration on therapy and potentially better outcomes following medication interventions. The targeted number of participants is 120 patients, and the study duration is expected to be 12 to 18 months.

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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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