

Biovica's DiviTum® TKa results presented at SABCS

Biovica, active in cancer monitoring, today announces that results from a study using the DiviTum® TKa blood test will be presented at the world's largest breast cancer symposium, SABCS, on December 8. The results support using DiviTum® TKa to predict the efficacy of CDK4/6 inhibitors in metastatic breast cancer.

"These results further strengthen the robustness of clinical evidence for use of the DiviTum® TKa test in metastatic breast cancer. Measuring TKa was done retrospectively after the study was completed and confirms the role of baseline TKa as a new marker for patient stratification. We look forward to helping patients by bringing DiviTum® TKa to market to provide a tool for physicians to better stratify and monitor patients," said Anders Rylander, CEO of Biovica.

"These results support using DiviTum® TKa as a tool to stratify metastatic breast cancer patients when initiating therapy and to identify patients with the best pre-requisites for improved survival during CDK4/6 inhibitor treatment," said Dr. Amelia McCartney, BSc, BA (Hons), MBBS, FRACP, first author and medical oncologist at Monash Health, Melbourne, Australia.

About the MA38 study

The study called MA38 was conducted by the Canadian Cancer Trials Group (CCTG) and investigated two different dosing schedules of the CDK4/6 inhibitor treatment palbociclib. Thymidine Kinase activity (TKa), as measured by the DiviTum® TKa assay, was used as a predictive biomarker to identify patients with a long duration on treatment and an extended overall survival in women with previously diagnosed HR-positive metastatic breast cancer (MBC).

180 women participated in the study and provided blood (serum) samples for DiviTum TKa analysis at baseline and after 12 and 24 weeks of palbociclib treatment. At baseline, the DiviTum TKa test identified patients who would go on to have a prolonged progression-free survival: patients with low TKa values (< median) had significantly longer progression-free survival than those with high (> median) TKa values, 16.3 vs 5.5 months (HR=2.43; 95% CI, 1.6-3.7; p<0.001). After 12 months, overall survival rate was 68% in patients with high baseline TKa vs 92% with low TKa. Evaluating samples drawn at 12 weeks into treatment demonstrated that high TKa values were significantly associated with worse overall survival (HR 2.0; 95% CI, 1.0- 4.0; p=0.03), with a similar trend for samples drawn at week 24.

The results will be presented on December 8 at the San Antonio Breast Cancer Symposium, SABCS 2022 (December 6-10).

MA38 study (NCT02630693)

Link: <https://clinicaltrials.gov/ct2/show/NCT02630693>

Poster Presentation Details

The poster (P5-02-27) will be presented on December 8 at 5:00 P – 6:15 PM CT at the San Antonio Breast Cancer Symposium, SABCS 2022 (December 6-10). Session Title: Poster Session 5: Prognostic and Predictive Factors: Biomarkers Predicting Tx Response: For Targeted Therapies

Serum thymidine kinase activity as a prognostic marker in women with metastatic breast cancer treated with two different schedules of palbociclib plus second-line endocrine therapy within the CCTG MA38 trial

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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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