

## DiviTum®TKa predicts clinical outcome of patients in BioItaLEE study

**Biovica today announced that the company's blood test DiviTum®TKa was highlighted in an oral presentation on June 6th at the ASCO Annual Meeting from the BioItaLEE trial. The study results suggest that TKa can predict patients' response to a CDK4/6 treatment.**

The BioItaLEE trial is a Novartis sponsored Italian multicenter study of 287 patients with hormone receptor-positive (HR+), HER-2 negative advanced breast cancer (ABC) treated with first-line (1L) ribociclib (RIB) and letrozole (LET).

The study concluded that testing patient blood samples for both TKa and ctDNA at baseline [D0] and day 15 of first treatment cycle [D15] was prognostic for progression free survival, and predictive for treatment response in the study patient group (BioItaLEE trial; NCT03439046).

These findings suggest that combining the early dynamic assessment of both ctDNA and TKa can improve outcome prediction in patients treated with RIB+LET. Patients with ctDNA+/TKa+ are strongly enriched for non-responders. TKa and ctDNA capture different features of tumor biological activity and their combination warrants further evaluation in relation to other treatments, settings, and diseases.

“The drug class of CDK4/6 inhibitors have contributed to significant progress in treating metastatic breast cancer. However, not all patients benefit equally. Some patients experience early progression, while others will remain on therapy for many years. Analysis of ctDNA and serum TKa in patients give independent contributions to prognostic and predictive stratification of patients for response to treatment and therapy selection. Combining the two provides even stronger results. Our study provides important results that using these biomarkers can offer oncologists valuable information for making treatment decisions. Further studies are warranted,” said Grazia Arpino, M.D., PhD., Associate Professor, University of Naples Federico II, UNINA Department of Clinical Medicine and Surgery.

“The primary objective of the BioItaLEE study was to identify biomarkers of response in advanced breast cancer patients receiving 1st line ribociclib + letrozole. We are extremely pleased to see that on-treatment, circulating TKa levels are strongly correlated with patients' response to ribociclib with a HR of 0.18 (p value <0.0001). On-treatment TKa values were also strongly predictive for a lack of response to ribociclib. Combining TKa values with ctDNA results improved the ability of both assays to identify non-responders even further. We have additional studies planned to follow-up on these impressive results. Our goal is to offer DiviTum®TKa as an affordable and convenient method to monitor treatment response in order to help oncologists make more informed treatment decisions for the benefit of their patients,” said Amy Williams, Ph.D., Global Head of Clinical Development and Medical Affairs at Biovica.

### **About DiviTum®TKa**

DiviTum®TKa shows thymidine kinase activity (Tka), as a measure of cell proliferation, in serum or cell cultures.

Thymidine kinase is an enzyme and in normal cells, the level is low. It rises, however, with cell division.

DiviTum®TKa is an assay for measuring cell proliferation and all that is required of the patient is a simple blood test.

## **Biovica – Treatment decisions with greater confidence**

---

Biovica develops and commercializes blood-based biomarker assays to evaluate efficacy of cancer treatments. Biovica's assay DiviTum® measure cell proliferation by detecting a biomarker in the blood stream. The assay has successfully demonstrated its capabilities to early evaluate therapy effectiveness in several clinical trials. The first application for DiviTum is monitoring of treatment for patients with metastatic breast cancer. Biovica's vision is that all cancer patients will get an optimal treatment from day one. Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum is CE-marked and registered with the Swedish Medical Products Agency. Biovica's shares are traded on the Nasdaq First North Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser, [info@fnca.se](mailto:info@fnca.se), +46 8 528 00 399. For more information please visit: [www.biovica.com](http://www.biovica.com).

## **Attachments**

---

[DiviTum®TKa predicts clinical outcome of patients in BioItaLEE study](#)