

DiviTum®TKa results from PYTHIA published in EJC

Biovica, active in cancer diagnostics, today announces that the positive DiviTum®TKa results from the European multicenter study PYTHIA have been published in the highly ranked peer-reviewed scientific journal European Journal of Cancer (EJC). The results demonstrate a predictive capacity of the assay after only two weeks of treatment and supports the use of DiviTum®TKa for optimized information and early therapy efficacy evaluation in metastatic breast cancer.

“The results support that serum TK activity can be a biomarker to identify those patients who will have an adverse outcome to the treatment with fulvestrant in combination with palbociclib, which represents the most current and active treatment standard for patients with metastatic, endocrine resistant estrogen receptor positive and HER2 negative breast cancer. TK activity measured after only two weeks of therapy gives us a strong indication on the clinical outcome independently from other clinical parameters. Even though further investigation in prospective comparative trials is warranted, these results are highly encouraging and highlight the potential of DiviTum®TKa to evaluate treatment efficacy already during the first weeks of therapy, and afterwards to monitor the disease.”, said Luca Malorni, Principal Investigator of the study at Prato Hospital, Italy.

“We are very proud to see the strong DiviTum®TKa results being published in EJC and want to thank IBCSG, BIG, Dr Malorni and all investigators for their dedicated work and collaboration. The publication in this highly reputable scientific journal is a great recognition for DiviTum®TKa. The PYTHIA study adds important prospective data that the assay, only two weeks into treatment, can evaluate the efficacy of endocrine therapy plus a CDK 4/6 inhibitor. The publication is an important step to establish DiviTum®TKa as a standard tool for monitoring treatment of metastatic breast cancer, to the benefit of patients and health care providers.” said Anders Rylander, CEO of Biovica.

As previously announced, results demonstrate that after two weeks of therapy, patients whose TK levels are suppressed, have a significantly better progression free survival six months from treatment start. The study investigators conclude that a high pre-treatment baseline TKa level and an incomplete suppression of TKa during the first treatment cycle can identify patients with poor prognosis and primary resistance to fulvestrant and palbociclib. The results strongly support a role for DiviTum®TKa as a patient stratification and monitoring tool. Serum TKa has an advantage over ctDNA-based approaches in being a technologically smoother and cheaper approach, with results obtainable in virtually every patient.

The PYTHIA study

PYTHIA (IBCSG 53-14/BIG 14-04; NCT02536742) is a downstream trial of the AURORA platform (BIG 14-01; NCT02102165) that started in 2015 at 19 centers in Belgium, Italy & UK. The study included a total of 122 patients and aimed to identify novel biomarkers of interest for patients treated with fulvestrant in combination with palbociclib. TK activity (TKa) was measured in serum samples collected before and after two and four weeks of treatment.

The PYTHIA study is the first prospective study in which DiviTum®TKa was assessed to address its capacity as a tool for early prediction of treatment efficacy for women with metastatic breast cancer. The study was conducted by the International Breast Cancer Study Group (IBCSG) in collaboration with the Breast International Group (BIG) with the financial support of Pfizer. Biovica provided financial support for sample collection and analysis in PYTHIA.

The results of the PYTHIA study were first presented at the world's leading breast cancer conference, SABCS, in early December 2020.

The European Journal of Cancer

The *EJC* is the official journal of the [European Organisation for Research and Treatment of Cancer \(EORTC\)](#) and the [European Society of Breast Cancer Specialists \(EUSOMA\)](#).

Link to article: <https://www.sciencedirect.com/science/article/pii/S0959804922000028?dgcid=coauthor>

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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, +46 8 528 00 399. For more information please visit: www.biovica.com.

Attachments

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