

## Multicenter study PYTHIA presents positive DiviTum®TKa results

**Biovica, active in cancer diagnostics, today announced that positive DiviTum®TKa results from the European multicenter study PYTHIA will be presented at the world's leading breast cancer conference, SABCS, in early December.**

The PYTHIA study is the first prospective study in which DiviTumTKa was assessed to address its capacity as a tool for early prediction of treatment efficacy for women with luminal metastatic breast cancer. The study was sponsored by the International Breast Cancer Study Group (IBCSG) and run in collaboration with the Breast International Group (BIG) with the financial support of Pfizer. Biovica provided financial support for conduct of the assays in PYTHIA.

“Our prospective study is the first to report that serum TK activity may be a biomarker able 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 (ER+) and HER2 negative (HER2-) 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.

These are the first results from PYTHIA (IBCSG 53-14/BIG 14-04; [NCT02536742](#)), 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 and was correlated with patient outcome.

Results demonstrate that after two weeks of therapy, patients for whom a suppression of TKa is detected have a significantly better progression free survival at six months from treatment start, i.e. 85 percent vs 17 percent in patients without strong suppression of TKa. The study investigators conclude that a high 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 PYTHIA study adds important prospective data that DiviTum®TKa only two weeks into treatment can evaluate the efficacy of endocrine therapy plus a CDK 4/6 inhibitor. We sincerely appreciate the work performed by BIG/IBCSG and are excited to see the results of this study, which, if confirmed, will have positive impact for patients and health care providers”, said Anders Rylander, CEO of Biovica.

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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](mailto:info@fnca.se), +46 8 528 00 399. For more information please visit: [www.biovica.com](http://www.biovica.com).

**Attachments**

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