

Biovica's DiviTum validated as a dynamic biomarker in metastatic breast cancer in collaboration with Institut Curie, Paris

Uppsala, Sweden, November 20, 2019. Biovica, active in cancer biomarkers, today announced that clinical data – demonstrating that DiviTum can be used as a dynamic, non-invasive biomarker for metastatic breast cancer patients treated with endocrine therapy and palbociclib – will be presented at the San Antonio Breast Cancer Symposium, December 10-14, 2019, the world's largest scientific congress focusing on breast cancer.

The prognostic value of DiviTum was assessed in a prospective study of 103 metastatic breast cancer patients treated from May 2016 until August 2018 at Institut Curie, Paris, with endocrine therapy and the CDK4/6 inhibitor palbociclib. Plasma samples were collected prior to treatment start and after four weeks of therapy. DiviTum was used to measure thymidine kinase activity in the samples (pTKa).

Low DiviTum values at four weeks was associated with longer progression free survival and overall survival compared with high values (10.4 versus 4.7 months, and not reached versus 20 months, respectively). Patients with a progression free survival below six months had a significantly higher pTKa level at four weeks (median 256 Du/L versus 100 Du/L).

“We have showed the clinical validity of DiviTum in an adequately designed prospective trial of combined targeted and endocrine therapies. We are encouraged by these promising results showing the potential of DiviTum to become a clinically useful dynamic biomarker for monitoring efficacy of palbociclib and endocrine therapy in patients with metastatic breast cancer”, said lead investigator Luc Cabel, MD, Institut Curie, Paris.

“We are proud to present great new DiviTum results in collaboration with globally renowned Institut Curie. The data presented in the study by Dr Luc Cabel and his colleagues constitute further important validation of DiviTum's capacity to monitor therapy efficacy in women with metastatic breast cancer. It supports the results from the TREnd study presented earlier this year, and our high expectations on DiviTum to become a standard biomarker in metastatic breast cancer. With DiviTum we want to contribute to improved patient outcome”, said Anders Rylander, CEO of Biovica.

Thymidine kinase 1 has a crucial role in DNA synthesis and cell proliferation. Prior studies have demonstrated that DiviTum has the potential to be a prognostic and monitoring biomarker in metastatic breast cancer treated with endocrine therapy +/- novel targeted therapy.

More data will be presented in the poster (P5-01-12) at San Antonio Breast Cancer Symposium entitled “*Plasma thymidine kinase 1 activity and outcome of ER+ HER2- metastatic breast cancer patients treated with palbociclib and endocrine therapy*”.

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In the event of contradictions or differences between the Swedish press release and this English translation of the Swedish press release, the Swedish text shall be given priority.

Biovica – Best Treatment from Day One.

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 Medicines 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.