PRESS RELEASE
July 30, 2022

Biovica receives FDA approval for DiviTum®TKa

Biovica, active in cancer diagnostics, today announces that FDA has granted 510(k) clearance for the product DiviTum®TKa as an aid in monitoring disease progression in previously diagnosed hormone receptor positive, metastatic postmenopausal female breast cancer patients.

"We are excited to have received the formal approval from FDA for our DiviTum®TKa assay, which is the first FDA cleared biomarker in this field. This is a very important milestone to realize the potential of the DiviTum®TKa product. We will now intensify our efforts to make DiviTum®TKa available for the benefit of breast cancer patients in USA before the end of this year," said Anders Rylander CEO of Biovica.

The DiviTum®TKa approval is based on clinical data from the SWOG S0226 study and a so-called clinical validation study based on SWOG S0226. In the clinical validation study, the assay demonstrated excellent capabilities to identify non progressors with high negative predictive values, NPV, of 96.7% for progression within 30 days and 93.5% for progression within 60 days. This means that 96.7% of patients with DiviTum®TKa measurements below the assay clinical cut-off, did not experience disease progression within the next 30 days.

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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.

This information is information that Biovica International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-07-30 13:00 CEST.

Attachments

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