PRESS RELEASE
August 26, 2020

Biovica successfully completes clinical validation for DiviTum® TKa FDA submission

Biovica today announces that the clinical validation of the blood test DiviTum® TKa has been completed, demonstrating the clinical value of the product. The clinical validation is the final part of Biovica's application for US market approval. Biovica remains on schedule to submit its regulatory filing during September 2020.

"We are very pleased that we have successfully completed the clinical validation in accordance with our timeline. DiviTum® TKa has met its predefined criteria. In the clinical validation, more than 1.700 samples from over 400 patients were analyzed. This is an important step towards finalizing our 510(k) application. This is a major milestone in making the product available for monitoring treatment of metastatic breast cancer and our intention is that DiviTum® TKa should be available to patients in the US early next year," 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, +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 2020-08-26 17:30 CEST.

Attachments

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