PRESS RELEASE
April 28, 2022

Biovica completes 510(k) submission for DiviTum®TKa to the FDA

Biovica, active in cancer diagnostics, today announces that the company has submitted its updated 510(k)-application to the U.S. Food and Drug Administration (FDA) to receive marketing authorization for the blood-based biomarker assay DiviTum®TKa.

Biovica's complete submission addresses the deficiencies identified by the agency on Biovica's original application, including the feedback received from FDA during the interactive process up until February 2022.

"We are glad to report that our team has worked thoroughly to provide all the remaining information that the FDA asked for. We look forward to making DiviTum®TKa available to breast cancer patients in US through our own CLIA certified lab as a 510(k)-cleared test, which we expect will happen later this year," said Anders Rylander, CEO of Biovica.

The expected outcome of the submission is either approval (clearance) or a request to submit more information.

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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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