PRESS RELEASE
November 13, 2020

Biovica's FDA submission will proceed to substantive review

Biovica, active in blood-based cancer diagnostics, today announced that the company's 510(k) submission to the US Food and Drug Administration (FDA) for the blood test DiviTum®TKa will proceed to substantive review when the COVID-19 related pause ends.

The FDA has previously informed Biovica about a reallocation of resources, due to a large volume of COVID-19 tests to be reviewed. Based on FDA's feedback Biovica expects the FDA to resume normal operations and start the substantive review in Q1 2021.

"The feedback from FDA is an important step in the process to DiviTum®TKa's 510(k) clearance. As soon as normal activities are resumed, the FDA can begin the review," 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 2020-11-13 15:20 CET.

Attachments

Biovica's FDA submission will proceed to substantive review