PRESS RELEASE
September 25, 2020

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

Biovica, active in blood-based cancer diagnostics, today announced that the company has filed a 510(k) submission with the U.S. Food and Drug Administration (FDA).

"The 510(k) submission is a major step towards bringing DiviTum®TKa to patients and we look forward to working with the FDA to achieve clearance of DiviTum®TKa. We see great value of the test in clinical practice, as DiviTum®TKa can enable provision of more tailored treatments for patients and for more efficient use of healthcare resources. Submission of the 510(k) application now keeps us on schedule for making the test available to breast cancer patients in early 2021," says Anders Rylander, CEO of Biovica.

The 510(k) submission follows a successful clinical validation of DiviTum®TKa in a large study that analyzed data from over 400 US and Canadian patients with advanced breast cancer, with data from over 1500 samples. The patients in this study had been diagnosed with metastatic breast cancer. All patients had hormone receptor positive disease, a common form of breast cancer affecting about 70 percent of patients.

DiviTum®TKa is currently sold as Research Use Only (RUO) in the USA. With the 510(k) clearance from the FDA, Biovica will be able to address the much larger IVD market.

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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 2020-09-25 10:00 CEST.

Attachments

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