PRESS RELEASE
January 29, 2021

FDA resumes review of DiviTum®TKa submission

Biovica, active in cancer diagnostics, today announced that the US Food and Drug Administration (FDA) has resumed its review of Biovica's 510(k)-submission for DiviTum®TKa.

"This is fantastic news on our journey to make the test available to US patients as early as possible. 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. We look forward to working with the FDA to achieve clearance of DiviTum®TKa. We are building our organization in the US, preparing for US launch in 2021," said Anders Rylander, CEO of Biovica.

Due to the high volume of Emergency Use Authorization (EUA) requests the FDA has received, and limitations on review resources, the FDA has also informed Biovica that it will not be able to complete the review within the usual 90 day MDUFA timeframe.

The 510(k) submission is based on 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 1700 samples. 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 2021-01-29 20:20 CET.

Attachments

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