PRESS RELEASE
March 14, 2022

Biovica establishes US CLIA lab to further strengthen DiviTum®TKa launch

Biovica, active in cancer diagnostics, today announces that the company will establish its own US CLIA lab for the launch of DiviTum®TKa on the US market. Biovica aims to have its lab operational and CLIA certified during third quarter 2022.

Biovica has decided to establish a CLIA lab in San Diego, California. A location has been identified and a lease for the premises has been signed. The lab will, after the 510(k) clearance, offer DiviTum®TKa-analysis, to Biovica's customers in the US.

By operating a CLIA lab, Biovica obtains full control of the selling process including management of reimbursement, ensuring value-based pricing and improved margins. It also allows for direct interactions with physicians and patients – the core DiviTum®TKa customers. In addition, an own lab offers an opportunity to build a sample biobank, an asset in future assay development, and will be an asset for Biovica's pharma collaborations.

"We see great advantages of operating a Biovica CLIA lab in US. Being in the driver's seat of the selling and reimbursement processes and in direct contact with physicians and patients will be critical success factors in our commercialization of DiviTum®TKa on the US market. There are several strong reference cases of successful launches of high value diagnostics tests using this model," said Anders Rylander, CEO of Biovica.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. Biovica's choice of San Diego as the preferred location is based on its center of excellence within pharmaceutical and diagnostic research and innovation.

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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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