Biovica receives CLIA certification

Biovica, active in cancer monitoring, today announces that the company's test laboratory in San Diego, California, has received CLIA certification allowing Biovica to begin commercial sales of DiviTum® TKa on the US market.

"The CLIA certification is a critical step for the launch of our recently FDA cleared DiviTum® TKa diagnostic test, and we can now begin our US commercial launch. Our team is committed to executing our go-to-market plan and look forward to contributing to the benefit of metastatic breast cancer patients," said Warren Cresswell, President of the Americas.

The Clinical Laboratory Improvement Amendment (CLIA) program, governed by the Centers for Medicare & Medicaid Services (CMS), is intended to regulate labs that perform laboratory testing and diagnostics on human specimens to maintain the accuracy, reliability, and reporting of patient test results. Biovica's certificate was granted by California Department of Public Health.

Biovica – Treatment decisions with greater confidence

Biovica develops and commercializes blood-based biomarker assays that help oncologists monitor cancer progression. Biovica's assay, DiviTum® TKa, measures cell proliferation by detecting the TKa biomarker in the bloodstream. The assay has demonstrated its ability to provide insight to therapy effectiveness in several clinical trials. The first application for the DiviTum® TKa test is treatment monitoring of patients with metastatic breast cancer. Biovica's vision is: "Improved care for cancer patients." Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum® TKa has received FDA 510(k) clearance in the US and is CE-marked in the EU. Biovica's shares are traded on the Nasdaq First North Premier Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser. 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 2023-02-08 08:00 CET.

Attachments

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