

Biovica expects CLIA certification during first quarter 2023

Biovica, active in cancer monitoring, today announces that the company expects to receive CLIA certification in during first quarter 2023.

The Laboratory Field Services (LFS) of California Department of Public Health (CDPH) has informed Biovica that it has scheduled an on-site visit of Biovica's new laboratory in San Diego, California, in January 2023. Thus, Biovica now expects to receive Clinical Laboratory Improvement Amendment (CLIA) certification during the first quarter 2023. This does not impact the planned and ongoing commercialization activities.

“Our team is looking forward to showcasing our laboratory to CDPH as a final step in the CLIA certification process. In parallel, we continue to advance our commercialization activities to drive demand for DiviTum® TKa. Our US customer facing team that was hired first of December will engage KOLs, regional thought leaders and medical oncologists while our Market Access team will engage targeted cancer centers. The DiviTum® TKa launch activities are well under way and our timeline is not impacted by this site visit. We expect to analyze the first DiviTum® TKa samples during the first quarter 2023,” said Warren Cresswell, Biovica President Americas.

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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 2022-12-13 22:00 CET.

Attachments

[Biovica expects CLIA certification during first quarter 2023](#)