

Biovica submits CLIA lab application for DiviTum®TKa launch

Biovica today announces that the company has submitted its CLIA lab application, marking yet another significant milestone for the US commercial launch of the recent FDA cleared test DiviTum®TKa. Biovica is now prepared to receive, analyze, and report results for its novel DiviTum®TKa diagnostic with capacity and capability to process samples nationwide.

“We are excited to make this submission for our CLIA lab certification for our new lab facility in San Diego, California. The submission for our CLIA application is a final, critical step to bringing this product into the US market and we look forward to launching DiviTum®TKa before year-end in USA,” said Warren Cresswell, President of the Americas at Biovica.

About DiviTum®TKa

DiviTum®TKa is an in vitro diagnostic device intended for the semi-quantitative measurement of thymidine kinase activity (TKa) in human serum. The assay is to be used as an aid in monitoring disease progression in previously diagnosed hormone receptor positive, metastatic postmenopausal female breast cancer patients.

DiviTum®TKa determines the enzymatic activity of thymidine kinase (TK) in human serum samples through technology that enables the assay to measure TK activity with high sensitivity. Biovica is currently engaged in several clinical studies to generate high-quality clinical data on the performance of DiviTum®TKa within different solid tumor types and cell-cycle regulating drugs.

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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. For more information please visit: www.biovica.com.

Attachments

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