PRESS RELEASE
July 25, 2025

Biovica launches DiviTum® TKa for use in early breast cancer

Biovica, active in blood-based cancer monitoring, today announces the launch of DiviTum Tka for use in early breast cancer for patients undergoing adjuvant therapy, available as a laboratory developed test (LDT) from its CLIA-certified laboratory in the US. The launch opens a new market indication, representing a potential fivefold expansion of the addressable market for DiviTum TKa.

"*We are very proud to be able to offer DiviTum TKa for use in early breast cancer to patients undergoing adjuvant therapy. This marks the beginning of a new phase in our commercialization with significantly increased market potential and the opportunity to improve treatment for an even larger number of patients.*" said Anders Rylander, CEO Biovica.

DiviTum TKa for early breast cancer is offered as an LDT test that has been validated by the Biovica CLIA lab in San Diego to fulfill the required precision and performance criteria. The test is supported by clinical data from trials consisting of more than 1.000 patients in early breast cancer[1, 2]. The test will utilize the existing PLA code including the Medicare price related to the code.

The test enables early identification of treatment response and resistance in hormone receptor-positive (HR+) patients treated with CDK4/6 inhibitors – the most prescribed drug class for this patient population in the metastatic setting that is included in guidelines also for adjuvant treatments in early breast cancer.

The launch opens a new market indication, which increases the addressable market for DiviTum TKa fivefold, corresponding to approximately USD 3 billion annually across key markets such as the US, Europe, and Japan.

More information is available here on divitum.com.

[1] " *Thymidine Kinase Activity in Serum Samples from PENELOPE-B*" presented at SABCS 2024.

[2] "*Interrogating serum thymidine kinase activity with CDK4/6 inhibitor-based therapies: real-world experience in the metastatic and adjuvant setting*" presented at SABCS 2024.

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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

Attachments

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