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PRESS RELEASE
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New AACR data expand evidence for TKa in immunotherapy-treated patients and CDK inhibitor dose optimization

Biovica, a leader in blood-based biomarkers for cancer treatment monitoring, today announces two poster presentations at the American Association for Cancer Research (AACR) Annual Meeting. The studies expand the evidence for circulating thymidine kinase activity (TKa), measured with Biovica's DiviTum® TKa assay, as a pharmacodynamic biomarker in oncology drug development. New data in immunotherapy-treated (ICI) lung cancer patients strengthen TKa's role in immuno-oncology research, while results from the CDK inhibitor study further validate the biomarker across preclinical models, clinical trials and real-world monitoring.

In the ICI study, patients with higher baseline TKa levels had significantly shorter progression-free survival (PFS) suggesting that circulating TKa may help identify patients with more aggressive disease. The findings indicate that circulating TKa may reflect tumor aggressiveness and could complement existing biomarkers such as PD-L1, by providing prognostic insight earlier in the treatment course.

"*These data further expand the clinical evidence for DiviTum TKa in patients treated with immune checkpoint inhibitors. Building on earlier studies, including melanoma, we now verify these findings in lung cancer. Together with our patent covering the use of TKa to predict response to ICI therapy, this strengthens our position to collaborate with pharmaceutical companies and participate in additional immuno-oncology studies,"* said Henrik Winther, SVP Pharma Services at Biovica.

Clinical trials and real-world evidence offer complementary perspectives on biomarker performance. While clinical studies evaluate biomarkers in controlled populations under strict protocols, real-world data reflect performance across individual patients in routine oncology practice. In the CDK study, real-world patient data aligned closely with results previously seen in clinical trials, supporting the robustness of TKa both as a pharmacodynamic biomarker in drug development and clinical practice.

"We actively support pharmaceutical companies in optimizing therapeutic dosing, now a core element of many of our collaborations. Using DiviTum TKa in dosing studies not only guides dose decisions but also clearly stratifies patients into responders and non-responders, a critical capability for companion diagnostic (CDx) development". said Anders Rylander, CEO of Biovica.

More on the studies

Study 1: TKa and immunotherapy outcomes (IMMUNOBLOOD)

The study investigated TKa in 94 patients with metastatic non-small cell lung cancer (NSCLC) treated with first-line immune checkpoint inhibitors (ICI), alone or in combination with chemotherapy.

Patients with low baseline TKa levels had a median PFS of 13.8 months, compared with 3.3 months in the high-TKa group ($p = 0.004$), using a predefined cutoff.

"Our study is the first to show a possible correlation between high plasma TKa levels and shorter PFS and overall survival (OS) in advanced NSCLC treated with first-line immunotherapy alone or combined with chemotherapy. The results support the potential role of DiviTum TKa in guiding treatment choice, and we look forward to continuing studying clinical use of TKa in NSCLC," said Federico Cappuzzo, Professor and Director of Medical Oncology at the National Cancer Institute Regina Elena in Rome.

Study 2: TKa as a pharmacodynamic biomarker for CDK inhibitor dose optimization

The study evaluated TKa across preclinical models, clinical trials, and real-world monitoring of patients receiving CDK4/6 and CDK2 inhibitors.

In CDK4/6 inhibitor-sensitive breast cancer cell lines, increasing palbociclib doses produced strong suppression of TKa, while resistant lines showed no significant changes. CDK-2 inhibition impact on TKa was demonstrated, with significant correlation between increasing drug exposure and decreasing TKa levels. Clinical observations also demonstrated correlations between drug exposure and reductions in TKa, consistent with inhibition of tumor cell proliferation.

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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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