BIOVICA®

TREATMENT DECISIONS WITH GREATER CONFIDENCE™

CE-IVD

Next-level metastatic breast cancer monitoring

The DiviTum® TKa blood test is the first and only FDA 510(k)-cleared TK activity profile test.

DiviTum® TKa

"The results from our study support using the DiviTum® TKa test to monitor efficacy during treatment and predict response to a CDK4/6 inhibitor. It is interesting to learn that DiviTum TKa can identify progression many months ahead of imaging."

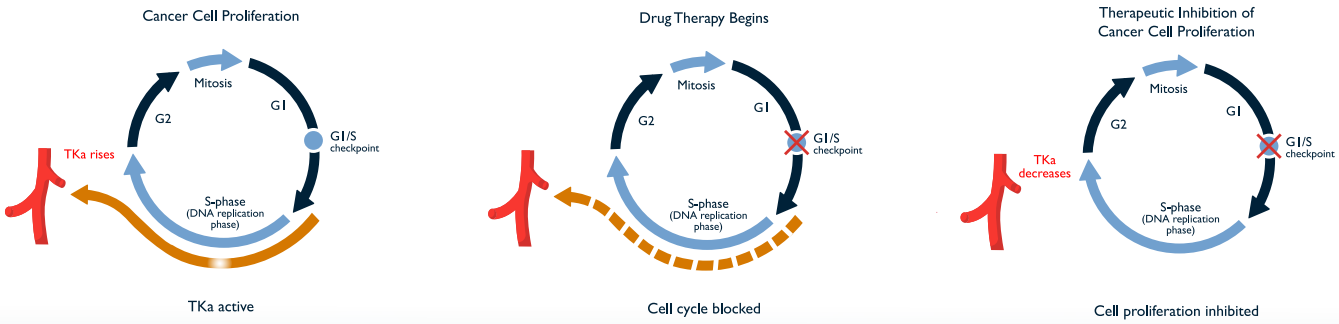
Luca Malorni, MD, PhD
Medical Oncologist, Prato Hospital, Italy

Prognostic for disease progression and overall survival (OS)[1, 2]

In postmenopausal female patients with metastatic HR+ breast cancer, a low TKa value is associated with the decreased likelihood of disease progression within 30 days or 60 days post testing.[1, 2]
…with the assessment of a simple blood sample, DiviTum® TKa can monitor and predict disease progression, PFS and OS in MBC patients receiving ET with or without CDK4/6 inhibitors.[2]

Thymidine kinase (TK) plays a key role in DNA synthesis and cell proliferation

Studies have shown that TK activity (TKa) is elevated in actively proliferating cancers[3, 4]



The DiviTum® TKa test can quantify the level of thymidine kinase released into the circulation from cell proliferation and tumor growth. This generates a DiviTum activity score which can offer important insights about the proliferative status of a patient's disease.

If the DiviTum® TKa test reveals a high TKa level in the blood, the oncologist can use this information in prognosis, in monitoring disease progression, and in patient management decisions.

Other breast cancer biomarkers

– **Conventional biomarkers** – such as CA 15-3 – are not expressed in all women with mBC[5]

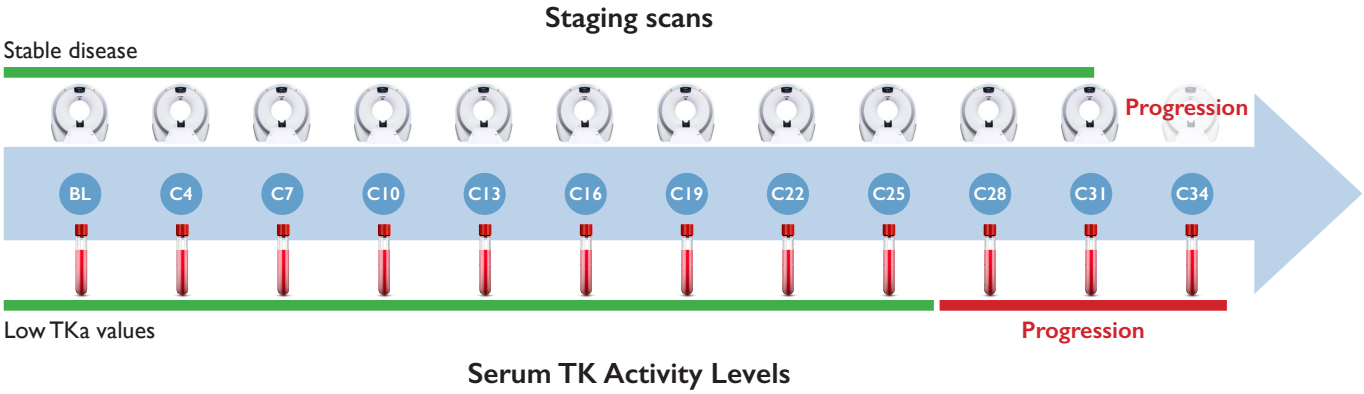
– **Low sensitivity of current imaging techniques:** Up to 40% of HR+ mBC patients have non-measurable disease[4]

– **Ki67** is a well-known proliferation (but not monitoring) biomarker, but has certain limitations (requires a biopsy, heterogenous expression).

DiviTum® TKa

The DiviTum® TKa test only requires a small amount of blood, does not require a biopsy, and can be tested repeatedly during therapy.

Correlation Timeline: TKa and CT-scans in mBC Patient[6]



The patient with a negative test result will, with 97% confidence, not experience any tumor progression in the next 30 days.[2]

The decreased likelihood of disease progression within 30 days or 60 days post testing[2] may suggest using the DiviTum® TKa test as an aid in-between imaging.

References

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2. Bergqvist M, et al. Biomarkers, 2023, DOI: 10.1080/1354750X.2023.2168063
3. Bitter EE, et al. Cell Biosci. 2020;10(1):138.
4. Larsson AM, et al. Sci Rep. 2020;10(1):4484
5. Gaughran G, et al, Breast Cancer Management, 2023 https://doi.org/10.2217
6. Krishnamurthy J, et al. npi Breast Cancer 8, 35 (2022)

DiviTum® TKa is CE labeled in Europe and FDA 510(k) cleared in the United States.

The DiviTum® TKa method and kit are protected under US Patent Nos. 8,765,378 and 9,376,707.
Patent protection in 49 countries
DiviTum® is a registered trademark of Biovica International AB

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