PRESS RELEASE
October 30, 2020

FDA resource reallocation impacts DiviTum®TKa timeline

Biovica, active in cancer diagnostics, today announced that the US Food and Drug Administration (FDA) has indicated that it is reallocating resources to COVID-19 impacting the timeline for completion of the review of Biovica's 510(k)-submission for DiviTum®TKa. The FDA currently estimates that the reallocation will last approximately 90 days during which time the FDA will not be able to continue reviewing Biovica's submission.

The FDA has informed Biovica that it is handling a large number of Emergency Use Authorization (EUA) requests for in vitro diagnostics (IVDs) to address COVID-19 and that a reallocation of resources is impacting the timeline for completion of the review of Biovica's submission. The FDA currently estimates that the reallocation will last approximately 90 days, but states that the precise duration is not known due to the uncertainty associated with the pandemic, including the volume of future IVD EUA requests the FDA may receive.

Biovica will receive monthly updates regarding the anticipated timeline for reallocation of resources back to non-COVID related activities and resumption of the submission review. When the FDA resumes the review, Biovica will provide an estimated time for completing the review.

"The ongoing pandemic is posing challenges for everyone in society, and we are not immune. We see the pause as temporary and hope that the FDA can resume normal activities as soon as possible. We continue to work toward making the test available to US patients as early as possible and are currently reviewing our timeline," said Anders Rylander, CEO of Biovica.

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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, info@fnca.se, +46 8 528 00 399. 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 2020-10-30 08:30 CET.

Attachments

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