BIOVICA

PRESS RELEASE
January 16, 2021

FDA resource reallocation continues to impact DiviTum®TKa timeline

Biovica, active in cancer diagnostics, today announced that the US Food and Drug Administration (FDA) has indicated that its previously communicated reallocation of resources to address COVID-19 continues to impact 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 another 90 days, approximately, during which time the FDA will not be able to continue reviewing Biovica's submission.

In October 2020, the FDA informed Biovica that its handling of a large number of Emergency Use Authorization (EUA) requests for in vitro diagnostics (IVDs) to address COVID-19 implied a reallocation of resources impacting the timeline for completion of the review of Biovica's submission. At the time, the FDA estimated that the reallocation would last approximately 90 days.

Due to the sustained volume of EUA requests the FDA has now informed Biovica that it is not yet able to resume the review of Biovica's submission. The FDA currently estimates that the reallocation will last annother 90 days, approximately, but continues to state 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 continue to 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 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.

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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 2021-01-16 12:48 CET.

Attachments

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