PRESS RELEASE
September 13, 2021

Biovica provides update on FDA application process

Biovica, active in cancer diagnostics, today announced that the company's expected timeline for its updated 510(k)-application to the US Food and Drug Administration (FDA) has been prolonged due to delay in response from FDA.

As Biovica is still waiting for required feedback from the FDA the company has not been able to submit its updated application yet. This means that the company most likely will not receive an answer from the FDA before the end of September, as previously communicated.

After submitting the response to the FDA, the expected outcome is either approval (clearance) or a request to submit more information.

"It is of course unfortunate that the FDA process is delayed. It is caused by the pandemic situation and unfortunately out of our control. We are ready to submit updates to the application but need to have patience and understanding about how the pandemic situation has affected processing times at the FDA. Thankfully, this is a short-term obstacle that will be overcome in due time," said Anders Rylander.

Contact

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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 2021-09-13 08:07 CEST.

Attachments

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