PRESS RELEASE
February 7, 2022

Biovica provides time-plan for FDA submission

Biovica, active in cancer diagnostics, today announces that it has received full feedback from the FDA on its updated 510(k)-application enabling a clear plan for the submission process. Biovica is now aiming for submission in May 2022.

As previously announced, Biovica has been waiting for required feedback from the US Food and Drug Administration (FDA) to be able to submit its updated 510(k)-application by a so-called complete response letter. The delay at the FDA was caused by the pandemic situation.

Now, Biovica has received feedback and has been informed that that there is only one question outstanding before the company can submit its updated application. Biovica has agreed with the FDA on which information Biovica needs to provide and is confident in being able to produce the required information for submission in May.

"This is great news as we now know which information we need to provide in order to complete our updated application. We believe that the interactive process that we have gone through with the FDA will be to our benefit in the review following the submission.", says Anders Rylander, CEO of Biovica.

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

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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 2022-02-07 21:48 CET.

Attachments

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