PRESS RELEASE
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Biovica completes analytical validation as part of FDA application

Biovica, active in cancer diagnostics, today announced that the analytical validation of the blood test DiviTum has been completed. The validation aims to verify technical and precision requirements defined in consultation with the US Food and Drug Administration (FDA). The analytical validation is an important part of the application for US market approval.

“It is with great satisfaction that we have carried out the analytical validation and passed the criteria we set up after discussion with the FDA. It is a big step towards completing our 510(k) application. Now the work on the clinical validation continues and as previously announced, we plan to submit our application in the third quarter of 2020. Our hope is thus that DiviTum will be available to patients in the US early next year," said Anders Rylander, CEO of Biovica.

A total of 15 extensive trials have been carried out to ensure DiviTum®'s performance. The validation has included analytical sensitivity, linearity, precision, stability, interference and usability. The trials have been carried out both at Biovica's laboratory in Sweden and at external laboratories in the US that are approved by the FDA, so-called CLIA laboratories.

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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.

Attachments

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