PRESS RELEASE
March 10, 2020

Biovica provides updates on FDA application

Uppsala, Sweden, March 10, 2020. Biovica, active in cancer diagnostics, today announced that the company intends to submit an FDA application for market approval of DiviTum in the third quarter of 2020 and not as previously announced in mid-2020.

"We are pleased with our results in the analytical validation, which is part of our FDA application and so far meet the criteria we have set. However, a component supplier has had delivery delays which means that we now anticipate being able to submit the FDA application a little later than previously expected," said Anders Rylander, CEO of Biovica.

So far, the results of the analytical validation meet the requirements set by Biovica. Due to delivery delays of a component that is part of DiviTum, production has been delayed. These problems have now been solved but mean that the analytical validation will not be completed until the second quarter.

Biovica's goal is to submit a 510(k) application for market approval to the US Food and Drug Administration, FDA, in the third quarter of 2020.

This information is information that Biovica International AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation 596/2014. The information was submitted for publication, through the agency of the contact persons set out below, on 10 March 2020 at the time stated by Biovicas's news distributor Cision at publication of this press release.

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Biovica – Best Treatment from Day One.

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.