PRESS RELEASE

28th of August 2019 7.55 CET

The path to 510(k) submission defined after FDA feedback

Biovica has completed the supplement II process which includes written feedback and physical meetings with the FDA in order to define the process for clinical validation for 510(k) submission for DiviTum®. Biovica also announces that an agreement with a leading oncology group has been signed. The agreement enables Biovica to analyze samples from a large, high impact, clinical trial within metastatic breast cancer. Biovica will use the results in the 510(k) FDA submission and has chosen to extend the time plan in order to include the results as an essential part of the submission.

Based on the feedback from the FDA, Biovica has now a clear path to a 510(k) submission and clearance for DiviTum. In the supplement II process, topics such as intended use, clinical validation plan and predicate device were discussed. This is the third and last step in the process, before submitting for 510(k) clearance.

The clinical validation will to a great extent be based on the data from a large, well-documented, US clinical trial of several hundred patients and multiple serial samples. Biovica has been given access to the patient samples through a recently signed agreement with a highly renowned US oncology group with high impact within the cancer.

The new trial will add significant value and improve the quality of the submission. Hence, Biovica has made the decision to extend the time plan for the 510(k) submission from end of 2019 to mid 2020 to be able to base the 510(k) submission on the new US trial, as this will add significant value to our submission.

"The feedback from FDA and the access to samples from the large US trial in collaboration with the well-established US oncology group offers an excellent opportunity for Biovica to have a solid foundation for our 510(k) submission and clinical validation. This important for future commercial success. A 510(k) clearance for DiviTum will make the product available for US patients and is an important step in fulfilling our vision to enable best treatment outcome for patients." says Anders Rylander CEO of Biovica

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This information is information that Biovica International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person(s) set out above, at 07.55 CET on August 28, 2019.

In the event of contradictions or differences between the Swedish press release and this English version the Swedish text will prevail.

Biovica – Best Possible Treatment from Day One.

Biovica develops and commercializes blood-based biomarker assays that improve monitoring of modern cancer therapies and predict patient outcome. The company's DiviTum® assay, a test for accurately measuring cell proliferation, has successfully demonstrated its capabilities to early evaluate therapy effectiveness in several clinical trials. Biovica aims to make best-possible-treatment from day one a reality. Biovica collaborates with world-leading cancer institutes as well as pharmaceutical companies launching next-generation therapies. The company is ISO 13485 certified for Quality Management Systems. DiviTum® is CE labelled and MPA registered. Appointed Certified Adviser to the company is FNCA Sweden AB, info@fnca.se, +46 8 528 00 399.