PRESS RELEASE

Monday, 27 August 2018 8.00

Biovica has completed supplement # 1 to the FDA with positive results

Biovica International AB (publ) today announced that the company received positive feedback from the FDA for the next step in the regulatory approval process. The feedback from the FDA ensures that the analytical validation is conducted in a manner that meets the FDA's requirements, so the product can get 510(k) clearance.

Biovica has previously communicated about a completed pre-submission to the FDA where risk class (II) and type of process (510(k) pre-market notification) were defined. Today, the company reports that also the next step in the process, supplementary 1, has been completed. Supplementary 1 comprise how analytical validation is to be carried out and how intended use of the product should be formulated to meet the requirements of the FDA.

Based on feedback from the FDA, analytical validation will be conducted to ensure test performance requirements will be met. In parallel, a supplementary 2 process to the FDA will be performed. It covers how clinical validation of the product will be carried out. As a next step, clinical validation will be performed before the FDA application will be submitted. This is planned to occur by the end of 2019 in line with what has previously been communicated. The clinical validation will be based on the already ongoing study program to a great extent.

The American market is important. Many new targeted treatments are introduced on the US market. However, new treatments do not help everyone. Hence, it is important with effective biomarkers in order to personalize treatments for best possible treatment outcome. Currently, evaluation using imaging technologies is standard practice which requires 3-4 months follow up in order to evaluate treatment efficacy. DiviTum® is developed to provide information on treatment efficacy faster than current practice. Results from clinical trials supports the conclusion that the assay can provide feedback on treatment effects already within 2-4 weeks. The assay requires a blood sample and the objective is to enable personalized treatments that results in better patient outcome and cost efficacy for the payers.

"The feedback from the FDA is important to us so that we can conduct analytical validation in a manner that ensures that we meet the FDA's requirements and in the long run receive a 510(k)-clearance so the product can benefit patients," says Karin Mattsson, Ph.D. R & D Director Biovica.

"It is a great achievement for Biovica to have passed another milestone in the regulatory approval process for the US market. This process and these milestones are important for meeting our objective, an approved product that can contribute to an individualized treatment for hormone-positive breast cancer and thus the best possible treatment results for the patients. " says Anders Rylander, CEO Biovica.

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 is FNCA AB. Biovica is traded at Nasdaq First North.

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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 08.00 CET on August 27, 2018.

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

Breast cancer
Each year about 8,000 Swedish women get breast cancer. About 1 in 10 women will suffer from breast cancer and the disease has become more common in the past twenty years. Four out of five who are diagnosed are over 50 years of age. Cancer is divided into different stages from early / local cancer to relapse / spread cancer. In early detection of breast cancer, the prognosis is good; four out of five are still alive five years after diagnosis. In the EU and the United States, approximately 450,000 women are diagnosed with metastatic spread breast cancer. Treatments for patients with metastatic breast cancer has improved in recent years. Those who suffer from metastatic breast cancer can now be offered many different treatments that can help delay disease progression. However, all treatments do not help everyone. Hence, it is important with effective biomarkers in order personalize treatments for best possible treatment outcome. Currently, evaluation using imaging technologies is standard practice which requires 3-4 months follow up in order to evaluate treatment efficacy. DiviTum® has been developed to provide information on treatment effect faster than current practice. Results from clinical trials supports the conclusion that the assay can provide feedback on treatment effects already within 2-4 weeks. The assay requires a blood sample and the objective is to enable personalized treatments that results in better treatment outcome and cost efficacy for the payers.

The market for DiviTum® in the United States and the EU for metastatic breast cancer is estimated to approximately SEK 6 billion by Biovica.