PRESS RELEASE

Monday, 4 February 2019

Biovica announces that the company's quality system is updated in accordance with ISO 13485:2016

Uppsala, Sweden, February 4, 2019. Biovica, develops and commercializes blood-based biomarker assays that improve the monitoring of modern cancer therapies and better predict patient outcome, announced today that the company has certified their Quality System according to the ISO13485:2016 standard for the development, manufacturing and sale of DiviTum® at the yearly surveillance audit with Biovica's notified body.

Biovica has been ISO certified since 2010. The update means that Biovica continues to fulfil the regulatory requirements for the development, manufacturing and sale of the company's product DiviTum®. The certification gives the company still right to CE mark their products for the European Market.

ISO 13485 is an international standard that defines the requirements of the Quality Management System (QMS) for manufacturers of medical device. The latest version, published in 2016, was aimed to further harmonize the QMS requirements globally within the medical device sector.

Biovica is currently preparing an FDA submission for DiviTum® to get approval and access to the US market. During the journey, adjustments have been made to meet the high demands of Quality System Regulation (QSR) that FDA currently apply.

At the same time, the FDA has announced that they will replace QSR with ISO 13485:2016 in the near future, which means that Biovica's certification according to ISO 13485:2016 is well in line with the FDA application that the company is preparing.

"The implementation of ISO 13485:2016 shows that Biovica successfully maintains the quality standard required to put DiviTum® on the market. The certificate is a milestone for our company and our work to get DiviTum® with the highest quality and safety at the market", says Wing Cheng, Market Access and Quality Assurance Director at Biovica.

"Biovica strives to produce DiviTum® that will meet regulatory and customer's expectation. With the implementation of the ISO 13485:2016, Biovica is fully aligned with the global regulatory requirements. The certification is a key step in the process of achieving FDA approval", commented Anders Rylander, CEO at Biovica.

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In the event of contradictions or differences between the Swedish press release and this English translation of the Swedish press release, the Swedish text shall be given priority.

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 Sweden AB, info@fnca.se, +46 8 528 00 399.