Press Release
26 May 2020 09:30:00 CEST

AroCell Submit to the FDA for AroCell TK 210 ELISA Clearance

AroCell AB (publ) announced today that a 510(k) application has been submitted to the U.S. Food and Drug Administration (FDA) for their AroCell TK 210 ELISA kit.

An introduction to the US market through 510(k) clearance of the AroCell TK 210 ELISA is in line with the company's previously communicated strategy for expansion in the USA. Today's submission confirms that the plan for 510(k) clearance of AroCell TK 210 ELISA by the end of 2021 applies.

AroCell TK 210 ELISA is currently sold as Research Use Only (RUO) in the USA. With the clearance from the FDA, AroCell will be able to penetrate the much larger IVD market.

AroCell TK 210 ELISA is a quantitative immunoassay kit for the determination of Thymidine Kinase 1 (TK1) in human blood. The ELISA format is simple and robust, requires no special instrumentation to perform and can easily be incorporated into standard laboratory processes. By utilizing monoclonal antibodies specific for the TK1 epitope TK 210, AroCell TK 210 ELISA brings improved sensitivity and specificity to the assay of this key biomarker. AroCell TK 210 ELISA provides new opportunities for studying cellular proliferation, disruption, and monitoring of therapy response in cancer.

"I am impressed of what we have accomplished over such a short time, in less than five months we have collected all data needed for the application", says Michael Brobjer, CEO of AroCell, and continues; "The submission for 510(k) and the subsequent clearance in the USA is a large step for our company. We are now preparing for the market launch together with our partners in the USA."

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About AroCell

AroCell AB (publ) is a Swedish company that develops standardized modern blood tests to support the prognosis and follow up of cancer patients. AroCell's new technology is based on patented methods to measure Thymidine Kinase 1 (TK1) protein concentrations in a blood sample. The TK 210 ELISA test provides valuable information mainly about the condition of cancer patients. This may help clinicians to optimize treatment strategies and estimate the risk of recurrence of tumor disease during the monitoring of the disease. AroCell (AROC) is listed at Nasdaq First North Growth Market with Redeye AB as Certified Adviser: Certifiedadviser@redeye.se, +46 (0)8 121 576 90. For more information; www.arocell.com

This information is information that AroCell is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-05-26 09:30 CEST.

Attachments

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