Press Release
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AroCell informs about FDA feedback regarding 510(k) application

AroCell announced today that after discussion with the FDA, concluded that the predicate device chosen for AroCell's 510(k) application is not possible given the intended use. This means that the 510(k) route is not applicable for this 510(k) application. Based on this new information from FDA, AroCell has decided to withdraw the 510(k) application in its current form. AroCell, in discussion with the FDA, will now evaluate the possibility of a so-called De Novo process used in cases when a predicate device is missing.

The reason why it hasn't been possible to find a predicate device for AroCell TK 210 ELISA in this 510(k) application and regulatory process is that the intended use is innovative and something similar is not on the market. This at the same time makes the product unique as it will meet a need where there is no product today.

"From a regulatory perspective, it was surprising to receive this information so late in the process. At the same time, the FDA has announced that they want to continue the dialogue regarding the product after we have now withdrawn this application. This is unusual but also positive as it enables us to analyze and map the way forward more quickly." says Peter Löwendahl, Senior Director Regulatory Affairs and continues, "The likely way forward is to apply for product approval according to the De Novo process. We intend to investigate this further and plan our continued activities regarding the indication of breast cancer".

"We have had a good and constructive dialogue with the FDA. AroCell TK 210 ELISA is a unique product with great potential in several different applications and indications. Our goal is that TK1 will become an integral part of cancer care." says Anders Hultman, CEO and continues, "The company is in an exciting phase and stands strong with several launched products and products under development as well as the opportunity for expansion into additional markets."

AroCell has a clear regulatory strategy for TK1 in the US. The goal is to gradually seek approval for the use of AroCell TK 210 ELISA for various cancer indications as new clinical data are generated. This is the starting point for AroCell's clinical program. The dialogue with the FDA regarding the indication of breast cancer will continue as described above. In line with the established strategy, the aim is to make several 510(k) applications in other indications such as for example prostate cancer.

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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

About TK 210 ELISA

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 and relapse in subjects with haematological and solid tumours.

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 2021-08-10 16:40 CEST.

Attachments

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