

## AroCell and FDA has had a pre-submission meeting for the 510 (k) clearance of AroCell TK 210 ELISA

**The path to FDA clearance of its product AroCell TK 210 ELISA is defined after an oral meeting with FDA. The aim of the meeting was to ensure that there was a common view of the documentation needed for the application.**

As previously has been communicated regarding the plans for a clearance and introduction to the US market a meeting with FDA was to be held to define the documentation needed for a successful process. AroCell has now had a pre-Submission meeting to ensure that there is a common view of the documentation needed for the submission. The meeting with the FDA confirmed that the requirements suggested by AroCell for the simpler application procedure 510 (k) can be used for the clinical indications AroCell intend to apply for.

This confirms that the previously announced plan for 510 (k) clearance of AroCell TK 210 ELISA and the expected clearance by the end of 2021 applies.

*"The communication with FDA confirms that our internal plan is in line with the requirements for FDA clearance according to the 510 (k) pathway. This is an important step for future commercial success in USA. A clearance for the TK 210 ELISA will make the product available for clinical samples from patients and is an important step for market penetration in USA",* says Michael Brobjer, CEO AroCell

### **About Thymidine Kinase 1**

Thymidine Kinase 1 (TK1) is a key enzyme in DNA precursor synthesis. It is upregulated during the late G1 phase and early S phase of the cell cycle and its presence in cells is an indicator of active cell proliferation. Increased levels of TK1 in the blood can indicate active cell proliferation as a consequence of abnormal cell turnover and cell disruption triggered by for example therapeutic agents.

### **Contacts**

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## About AroCell

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AroCell AB (AROC) 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](mailto:Certifiedadviser@redeye.se), +46 (0)8 121 576 90. For more information; [www.arocell.com](http://www.arocell.com)

## Attachments

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