Press Release
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FDA resumes review of AroCells 510(k) submission

AroCell announced today that the US Food and Drug Administration (FDA) has resumes AroCells 510(k) submission after the impact of relocation due to the COVID-19 pandemic.

Due to the sustained volume of EUA (Emergency Use Authorization) requests and the continued importance of testing in the response to the pandemic, FDA delayed all the submission reviews, which now are resumed.

"We are excited about this news. This is an important step for future commercial success in US for AroCell. Clearance of the 510(k) for AroCell TK 210 ELISA will make the product available for clinical testing of patient samples and is an important step for market penetration in US", says Anders Hultman, CEO of AroCell.

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 2021-04-16 08:32 CEST.

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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

Attachments

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