AroCell informs about dialogue with the FDA

AroCell AB announced today that a dialogue has been held with the U.S. Food and Drug Administration (FDA) regarding the 510(k) submission that the company submitted on May 26, 2020. In the dialogue with the FDA, AroCell received questions regarding the 510(k) submission. AroCell intends to process the questions promptly and update the application within a few weeks.

"This type of dialogue with regulatory authorities is not uncommon when applying for 510(k). We have had a constructive dialogue with the FDA and we are now focusing on addressing the questions and updating the application in accordance with FDA recommendations," says Michael Brobjer, CEO of AroCell.

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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 2020-09-22 17:00 CEST.

Attachments

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