FDA informs AroCell about the delayed timeline

AroCell announced today that the US Food and Drug Administration (FDA) has informed regarding the impact of the COVID-19 pandemic and the reallocations of staff is leading to a prolonged timeline for reviews of submissions. FDA at the moment expects 90 days reallocation time that will prolong AroCells 510(k) submission review.

FDA's Center for Devices and Radiological Health (CDRH) has been actively engaged in responding to the current pandemic caused by a novel coronavirus (SARS-CoV-2) and the associated disease it causes (COVID-19). And due to a large number of Emergency Use Authorization (EUA) requests that they have received for in vitro diagnostics (IVDs), and the reallocation of staff and resources are impacting the timeline for the reviews of submissions.

AroCell will receive updates regarding the anticipated timeline for the resources on the non-COVID related activities.

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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 2020-10-30 10:23 CET.

Attachments

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