

FDA informs about another delay due to Covid-19

AroCell announced today that the US Food and Drug Administration (FDA) has informed once again that the impact of the COVID-19 pandemic and the reallocations of staff is leading to an even greater prolonged timeline for reviews of submissions. FDA informed that the delay is prolonged with another 90 days and will prolong all 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). They state that due to the sustained volume of EUA (Emergency Use Authorization) requests and continued importance of testing in the response to the pandemic, they are not yet able to resume the review 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

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Attachments

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