

Updated timetable for the glucose and LDH products

Calmark Sweden AB announces today that the timetable for the development projects related to the products Neo-Glucose and Neo-LDH have been updated. These products will receive their CE conformity markings during the second quarter at the earliest, not during the first quarter as previously disclosed. The Company has prioritized its resources in order to finalize the CE marking of the first product, Neo-Bilirubin, which is projected to be achieved during the first quarter of 2020.

A clinical trial with bilirubin is ongoing at Södersjukhuset at the moment; it is expected to be completed mid-March, as previously disclosed on 28 January. When it is completed, regulatory documentation will be compiled in order to achieve the CE Mark approval.

Calmark already has The Swedish Ethical Review Authority's approval for clinical studies on the Company's other biomarkers, glucose and LDH, as well as an agreement with the children's hospital Sachsska barnsjukhuset, part of Södersjukhuset, to conduct them. These trials are planned to commence during spring.

"It is important for us that the sales launch of our first product, Neo-Bilirubin, is not delayed. This is also the product which we consider to have the most substantial market potential. The development of the Neo-Glucose and Neo-LDH products are progressing, but there is still some work remaining before we can enter the validation and verification stage. Only then can we start the clinical trials. According to the updated plan, we should be able to complete these before the summer holidays," says Anna Söderlund, CEO.

This information is information that Calmark Sweden AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on 13 February 2020, 16:30 CET.

Every care has been taken in the translation of this document. In the event of discrepancies, the Swedish original will supersede the English translation.

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Calmark Sweden AB is a medical technology company developing a point-of-care (POC) analyzis method with easier and faster sampling of medical conditions in newborns. The unique test platform, which consists of a reader and single-use products, is expected to be ready for launch in 2020 when three important POC tests are introduced. The WHO estimates that 1.5 billion children will be born worldwide by 2030. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter healthcare chains. In less developed healthcare systems, the product helps save lives. Calmark aims to become the global leader and ultimately to offer all relevant POC tests for the first period of life, regardless of where in the world a baby is born. Read more about Calmark www.calmark.se/eng/home.