



Calmark's trial at Södersjukhuset closed

The clinical trial with Calmark's first product, Neo-Bilirubin, which has been carried out by the research unit at the children's hospital Sachsska barnsjukhuset, part of Södersjukhuset AB, Stockholm, is now successfully closed with satisfactory results. Monitoring of the trial was conducted by Scandinavian CRO. The remaining step before Neo-Bilirubin can obtain its CE mark is the preparation of final reports, which is projected to take approximately two weeks.

The first patient was included in the study on 23 December. Since then, the research unit, in cooperation with the clinical wards involved, have been able to include infants on a continuous basis.

The extraordinary circumstances caused by the COVID-19 outbreak have forced Södersjukhuset to reprioritize resources. As a result, the trial could not proceed in the same way. Because of the disruption, the 40 duplicate tests which were planned to be included when the study was initiated could not be obtained. The Company's assessment is that the number of infants included in the study is fully sufficient to demonstrate that the product meets the technical requirements. This consideration is also based on the extensive verification and validation carried out in Calmark's laboratory.

The decision to close the study prematurely was made, after careful consideration, on 6 April, as the monitoring had been carried out.

This information is information that Calmark Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 16:45 CET on 6 April 2020.

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) analysis 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.