Verification phase for Calmark's first product completed

The verification phase of the development project for Calmark Sweden AB's (publ) first product, Neo-Bilirubin, was completed today with successful results from all sub-phases regarding the function and performance of the product.

CE conformity marking and the development of medical technology products follows a seven-step process, where the first three steps involve identification of requirements specification and development to cover them. The product is then verified against the prescribed requirements and validated by potential end users (steps four and five). The development project is then closed, and design transfer to production is done in step six. In the final and seventh step, the product formally obtains its CE mark approval.

The verification and validation phases for the upcoming CE marking of Calmark's first product, Neo-Bilirubin, were both initiated on 8 October 2019. Today, the verification of the products function and performance, demonstrated through more than 3,000 tests performed in Calmark's laboratory, was completed. Both the reader and the single-use test have undergone comprehensive testing to ensure, among other things, accuracy, precision, interference, stability, transport, safety and standards compliance. This effort further includes an extensive amount of documentation, which has now been completed.

Parts of the validation phase have been completed as well, but this phase also includes the clinical study still underway at Sös, which is expected to be concluded within the first quarter. Newborn infants with suspected elevated levels of bilirubin are included on a voluntary basis in the daytime, with assistance of the research unit at the children's hospital Sachsska barnsjukhuset.

"*The milestone reached today is immensely important for Calmark. We have nowensured that our first product complies with all regulatory requirements regarding function and performance. We have conducted a large number of tests in our laboratory, and our development team has made a tremendous work,*" says Anna Söderlund, CEO of Calmark. "*Up until today, the Sös study, which is the most important activity that still remains, has not been affected by the ongoing Coronavirus outbreak; we fully understand that Sös may need to refocus their priorities, and we are monitoring the situation closely as it develops.*"

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 14:30 CET on 13 March 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) 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.