Press release
Lund May 5, 2023

Scandinavian ChemoTech's product, IQwave 3.0 CE system, can continue to be sold in the EU without being re-certified until 2028

A Change of transition times for legacy products have been published by the European Committee (EC). This gives medical device products, approved according to the Medical Devices Directive (MDD) requirements, a possibility to continuously be released on the market for a certain time, depending on their risk class. For Scandinavian ChemoTech, this implies that the IQwave 3.0 CE system can be placed on the market for another five years, without renewed certification.

The IQwave system is classified to IIb which extends this period until December 31, 2028, when the new European Medical Device Regulation (MDR) comes into effect. ChemoTech´s present plan is to start the full MDR documentation in 2025.

Certain routines and requirements set by MDR is also applicable for legacy devices and those are already implemented for the product documentation and ChemoTech´s Quality Management System.

This enables Scandinavian ChemoTech to focus on commercialization and clinical developments associated with the IQwave™ system for the coming years and leads to estimated cost savings in the next two years amounting to more than 1 million SEK.

"It feels good to be able to re-allocate these funds to marketing efforts in the current development phase, where our focus is on bringing significant sales. The possibility of postponing this re-certification means that our plans to be cash flow positive in the near term gives the opportunity to self-finance the MDR documentation when the time comes to complete it.", says Mohan Frick, CEO of Scandinavian ChemoTech.

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Scandinavian ChemoTech AB (publ)
ChemoTech is a Swedish medical technology company based in Lund that has developed a patented technology platform to offer cancer patients access to a new treatment alternative, Tumour Specific Electroporation™ (TSE), available for treatment of both humans and animals. There are a large number of cancer patients whose tumours for various reasons cannot be treated by conventional methods but where TSE can be a solution. Therefore, the company continuously

evaluates new opportunities and areas of application for the technology. ChemoTech's shares (CMOTEC B) are listed on Nasdaq First North Growth Market in Stockholm and Redeye AB is the company's Certified Adviser. Read more at: www.chemotech.se.