PolarCool takes an important step towards launching in the US

The med-tech company PolarCool AB (publ.) announces that today they have submitted a formal De Novo application to the US Food and Drug Administration (FDA), to prepare for a launch in the USA.

The company announces today that a De Novo-application for the PolarCap® System has been submitted to the FDA. This is an important step ahead of the upcoming company launch in the United States, where the goal is to initiate a full-scale investment in the US American market in 2025-2026. The company already has an employee stationed in the US with the task of preparing the launch. A market approval from the FDA is a requirement to be able to sell medical devices on the US market.

In the United States, approximately 3.8 million concussions occur annually, with the North American market for concussion treatment valued at approximately SEK 3.4 billion annually. The US market is also particularly interesting with the extensive presence of universities and colleges, where many sports are played in conjunction with academic studies. With over 3,500 of these types of schools, there is significant potential for implementation of the PolarCap® System at these institutions.

PolarCool CEO Erik Andersson comments;

- *One of our most important goals is to launch the PolarCap® System in the US. Therefore, it feels fantastic that today we submitted a formal application to the FDA and thus took an important step forward to achieve this. The US market has large potential and is a key market for our expansion. Above all, we look at the biggest sports such as American football and ice hockey, where the incidence of concussion is high and the need for solutions is large. Already today, we notice a great interest in the PolarCap® System both from universities and medical representatives. Therefore, I have very high hopes for our upcoming launch.*

PolarCool decided in October 2022 to focus on a De Novo-application as a result of the clinical results from the 5-year study with the PolarCap® System, in consultation with the FDA. The strong study results enables the PolarCap® System to be approved as a treatment against a purely medical indication, "concussion", as a new unique product on the market, a so-called first-mover. At the end of 2023, PolarCool received an MDR certificate both for the company's quality management system (QMS) and for the product PolarCap® System, which together with the recently secured financing enabled PolarCool to complete work on the application. PolarCool will now cooperate with the FDA to obtain this approval and in parallel prepare the upcoming launch.

This information is information that PolarCool (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 herein, on September 26th, 2024.

For more information
Erik Andersson – CEO PolarCool AB (publ.)
+46 – 73 860 57 00
E-mail: erik.andersson@polarcool.se

About PolarCool AB (publ.)

PolarCool AB (publ.) is a medical device company that develops, markets, and sells products for sports medicine. The company focuses on treatment of concussive and sub-concussive brain injury with the portable cooling device PolarCap® System. PolarCool AB (publ.) is based in Lund, Sweden, and its shares are listed on Spotlight Stock Market.