

PAXMAN supplements application for expanded FDA clearance in the USA

PAXMAN AB (publ) has supplemented the company's premarket notification application to the US FDA for an expanded indication by responding to a request for additional information. The application seeks to expand use of the company's scalp cooling to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors.

The additional information, that has been submitted to and received by the FDA, consists of an in-depth analysis of the clinical results provided as the basis for the expanded indication.

"The clinical results for our expanded FDA application demanded a more thorough analysis for optimal overview than we expected. This has led to a longer regulatory process in this case, but it also creates potential to speed up upcoming applications in other regions," says PAXMAN's CEO Richard Paxman.

PAXMAN expects the FDA to be able to complete the application process without the need for additional amendments.

For more information, please contact:

Richard Paxman, CEO

Tel: +44 7968 020641

Email: richard@paxmanscalpcooling.com

www.paxman.se

This information is such information that PAXMAN AB (publ) is obligated to publish in compliance with the EU market abuse regulation. The information was provided by the above contact person for publication on the 8th of May 2018 at 10.35 CET.

About PAXMAN

The PAXMAN Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. With close to 3,000 systems delivered in to hospitals, clinics and treatment centres around the world, PAXMAN is the leading supplier of Scalp Cooling technology. PAXMAN's scalp-cooling cap is made from lightweight, biocompatible silicone that is soft and flexible, providing a snug yet comfortable fit during treatment. PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden), with subsidiaries in Huddersfield (UK) and Houston, Texas (US).

The PAXMAN share is listed on Nasdaq First North. FNCA Sweden AB is the company's Certified Adviser.