

## **PAXMAN announces FDA clearance for an expanded indication of its scalp cooling system in the US**

**PAXMAN's advanced scalp cooling system has now been cleared by the US Food and Drug Administration (FDA) for use during treatment of patients with solid tumours. The expanded FDA clearance substantially increases the potential number of new cancer patients per year that the system can be marketed to in the USA – from an estimated 250,000 breast cancer patients to over one million breast cancer and solid tumour cancer patients.**

PAXMAN's 510k application for expanded use of its scalp cooling system was submitted to the US Food and Drug Administration (FDA) in October 2017, and was thereafter supplemented in early May in response to a request for additional information and analysis.

To date PAXMAN has installed around 225 scalp cooling systems in the US since its original FDA clearance in April 2017, and the order book contains more than 65 systems awaiting delivery and installation. The expanded FDA clearance undeniably paves the way for PAXMAN to further stimulate patient enrolments for systems already installed, but also increases the likelihood of existing PAXMAN locations ordering additional systems.

- I am very satisfied that we are now able to offer our important technology to several times as many patients as before in the USA, as it has proven to have a hugely positive impact on their cancer journey. Our scalp cooling system is already cleared for solid tumours in almost every other market where we are established to date, so this clearance is key to our continued global expansion, says PAXMAN's CEO Richard Paxman.

### **For more information, please contact:**

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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 7th of June 2018 at 17:15 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 more than 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.*