



Press release

Dignitana AB (publ) | Lund – October 21, 2014

Dignitana AB in meeting with the Food and Drug Administration (FDA)

Dignitana AB, a world leader in medical scalp-cooling technology for reducing hair loss related to chemotherapy, is pleased to announce that it has had a formal meeting with the Food and Drug Administration (FDA) in Washington D.C. The intention was to clarify a number of queries regarding the final clinical module. The meeting was held in a positive atmosphere, and the company will be submitting the final module which contains clinical data by the end of November.

The clinical study that Dignitana has performed is creating interest in the United States. In the latest of several news articles, CBS News is following a patient who was treated with scalp cooling as a part of the study.

Link: <http://www.cbsnews.com/news/chemo-cap-helps-breast-cancer-patients-keep-their-hair/>

Dignitana is conducting a Premarket Approval (PMA), a regulatory process with the aim to obtain product and market approval for the DigniCap® System in the United States (U.S.) by the Food and Drug Administration (FDA). Dignitana obtained approval from the FDA to implement a module based registration. The first two modules containing quality routines for product development and manufacturing have already been submitted. The third and final module will contain clinical data from the ongoing Pivotal trial. Thereafter FDA will review the documentation and decide on a product and market approval.

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About Dignitana AB (publ)

Dignitana is a Swedish public company, based in Lund, and manufacturer of medical cooling devices. Our core product - the DigniCap® System - is a patented scalp-cooling system for preventing or reducing hair loss for chemotherapy patients. Dignitana is continuously researching and developing new products and use for the DigniCap® System. Dignitana AB is listed on the OMX Nasdaq First North Stockholm. For more information visit www.dignitana.com

About the DigniCap® System

The DigniCap® System protects cells, and ultimately your hair, by reducing the concentration of chemotherapy being delivered to your scalp area. The DigniCap® System is developed to provide continuous cooling with high efficacy, safety and acceptable patient comfort.