



Press release

Dignitana AB (publ) | Lund - August 06, 2014

## **Dignitana Completes Patient Recruitment in a Multi-Center Pivotal Trial for FDA approval in the United States**

### **Dignitana on track with U.S. Premarket Approval (PMA)**

**Dignitana AB**, a world leader in medical scalp-cooling technology for reducing hair loss related to chemotherapy, is pleased to announce that it has completed patient recruitment in the multi-center pivotal trial of the patented DigniCap® System.

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 and will be submitted as soon as the results are available. Thereafter FDA will review the documentation and decide on a product and market approval.

#### **Details of the clinical study**

In the summer of 2013 a multi-center Pivotal trial, which is part of the ongoing Premarket Approval process, was initiated at the following hospitals:

1. UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, California
2. Weill Cornell Breast Center, New York, New York
3. Beth Israel Medical Center, Comprehensive Cancer Center, New York, New York
4. Wake Forest University School of Medicine, Winston-Salem, North Carolina

#### **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](http://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.



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5. UCLA Hematology/Oncology Santa Monica, Santa Monica, California

All patients that are to receive scalp-cooling treatment with DigniCap® system were included before the summer, and now all control patients are included. The inclusion of control patients gained momentum after all scalp-cooling patients were included and scalp-cooling treatment was no longer an option.

Scalp-cooling patients will come back one month after completion of their last chemotherapy treatment for a follow up visit. Hair loss, compared to baseline (i.e. before the first chemotherapy treatment), will be assessed during this visit. Control patients, that are receiving chemotherapy without scalp-cooling treatments, are evaluated if and when they experience hair loss.

"To have recruited all patients is a milestone for our company and a major step forward in our PMA process." said Erika Bågeman, Dignitana AB's Clinical Affairs Manager.

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