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DIGNITANA RECEIVES U.S. FDA DE NOVO CLEARANCE FOR THE DIGNICAP[®] SCALP COOLING SYSTEM THAT REDUCES HAIR LOSS RELATED TO CHEMOTHERAPY FOR WOMEN WITH BREAST CANCER

Dignitana Brings First and Only U.S. FDA-Cleared Scalp Cooling System to Market

Alternative to one of the most devastating side effects feared by women with breast cancer will soon be available at leading cancer centers nationwide

DALLAS, TX, DECEMBER 8, 2015—Dignitana, a world leader in medical scalp-cooling technology, announced today that the U.S. Food and Drug Administration (FDA) has granted the company's de novo application to market the DigniCap[®] scalp cooling system, designed to reduce the severity of chemotherapy-induced hair loss. After rigorous clinical studies and wide use overseas the DigniCap[®] scalp cooling system is now FDA-cleared for use in the United States. The system, which is the only such device to have **completed an FDA approved multi-center clinical trial**, is used by patients undergoing chemotherapy infusion, and is cleared for use with treatment regimens associated with breast cancer.

Dignitana is currently finalizing agreements with major cancer centers and community oncology groups across the country so that they will be able to offer DigniCap[®] to patients as soon as possible. Prior to clearance, the DigniCap[®] scalp cooling system was clinically studied in women with breast cancer at some of the most prestigious medical centers in the nation, including:

- **UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, California**
Principal Investigator Hope S. Rugo, M.D.
- **Wake Forest Baptist Medical Center, Winston Salem, NC**
Principal Investigator Susan Melin, M.D.
- **Weill Cornell Breast Center, New York, NY**
Principal Investigator Tessa Cigler, M.D.
- **Mount Sinai Beth Israel, Comprehensive Cancer Center, New York, NY**
Principal Investigator Paula Klein, M.D.
- **UCLA's Jonsson Comprehensive Cancer Center, Santa Monica, CA**
Principal Investigator Sara Hurvitz, M.D.

“Some of today's most powerful, life-saving chemotherapy treatments still cause complete hair loss, a side effect that many women consider to be emotionally devastating,” said Dr. Hope S. Rugo, Principal Investigator for the study and Director of Breast Oncology and Clinical Trials Education at the UCSF Helen Diller Family Comprehensive Cancer Center. “For the past several years, we've worked closely with Dignitana to conduct rigorous clinical trials that demonstrate the safety and effectiveness of the DigniCap system. This FDA clearance means that for many cancer patients in the U.S., chemo-induced hair loss will no longer be a distressing concern.”

In the U.S. clinical trial 7 out of 10 patients with early stage breast cancer kept at least 50% of their hair. With regards to safety, no severe adverse events were reported. While most patients had a feeling of chilliness during the cooling down period only 3 out of 106 trial participants discontinued for this reason. A patient reported satisfaction score (ranked from 0 to 100, with 100 being “completely satisfied”), showed a mean score of 87.5 satisfaction with the decision to use scalp cooling, a mean score of 70.9 for hair quantity, and a mean score of 69.1 for satisfaction with hair quality. In the U.S. trial, scalp cooling was evaluated mainly on regimens including taxanes (such as paclitaxel and docetaxel) but outside of the U.S. there is also experience from scalp cooling with anthracyclines (such as epirubicin and doxorubicin).

The DigniCap® scalp cooling system features a patented tight-fitting silicone cooling cap that is placed directly on the head, and an outer neoprene cap that insulates and secures the silicone cap. The cooling cap is connected to a cooling and control unit with touch screen prompts. A liquid coolant circulates throughout the silicone cap, delivering consistent and controlled cooling to all areas of the scalp. The cap is fitted to the head, and the temperature of the scalp is lowered, resulting in vasoconstriction with reduced delivery of chemotherapy to the scalp, as well as reduced cellular uptake of drugs due to decreased intra follicular metabolic rate. These factors together reduce the risk of hair loss.

DigniCap® is the only system to offer gradual cool down and effective scalp cooling at temperatures above freezing for greater patient comfort. Two built-in cap sensors continuously monitor scalp temperature and allow the system to maintain optimal cooling throughout the scalp cooling treatment. A third built-in safety sensor ensures the cooling temperature as measured on the scalp never drops below the freezing point of 32° F (0° C).

“We are thrilled to be able to advance the science of hair preservation for women who must undergo chemotherapy and to find ways to make life saving treatments more tolerable,” said Laura Esserman, M.D., M.B.A., Professor of Surgery and Director of the Carol Franc Buck Breast Care Center at the [UCSF Helen Diller Family Comprehensive Cancer Center](#). “An FDA approved product that makes scalp cooling available for women across the country is extremely good news.”

“This FDA clearance means that finally, breast cancer patients in the U.S. will have access to a convenient, safe and scientifically proven option for reducing chemotherapy-induced hair loss,” said Jan Richardsson, Chief Executive Officer for Dignitana. “We are tremendously excited to be able to offer this state-of-the-art technology to hospitals and infusion centers across the U.S.”

“Working with the professionals at our clinical trial sites has given us a significant head start in learning how best to provide the DigniCap® scalp cooling system here in the U.S.,” said Dignitana Inc., COO Bill Cronin. “Additionally, we are fortunate to have attracted a talented group of professionals with scalp cooling experience, ready to help our future infusion center clients offer this valuable therapy option to patients as efficiently and as smoothly as possible. We are gratified and excited that after such an extensive and rigorous development and investigational process we are now moving forward to market the DigniCap in the U.S.”

“I am extremely excited to finally be able to offer patients scalp cooling during chemotherapy which allows them to retain normalcy and privacy in their lives,” said Paula Klein, M.D., Medical Director, Breast Cancer Clinical Trials, Mount Sinai Health System. “I am proud that Mount Sinai Beth Israel was one of five cancer centers to participate in the important clinical trial that has led to this approval. Losing hair is one of the more distressing side effects of chemotherapy and this is a game changer for many.”

Dignitana will be working actively with the payor community with the hopes of gaining coverage and payment for its product/service. In addition to working on this issue with the payor industry, Dignitana is also working to engage philanthropic organizations foundations and potential corporate donors and sponsors to help ensure that as many patients as possible are able to consider scalp cooling technology as part of their care regimen. Some donors are already working directly with individual medical centers, such as the UCSF Helen Diller Family Comprehensive Cancer Center, to ensure that patient expenses can be subsidized.

“I am profoundly grateful to be supporting a system that is able to minimize the psychological impact of an overwhelming diagnosis,” said Ingrid Tauber Ph.D., Clinical Psychologist and President of the Laszlo Tauber Family Foundation. Dr. Tauber provided funding to UCSF to get the first trial underway and has since created a fund to help support patients who want to use the DigniCap® scalp cooling system during their chemotherapy infusions at UCSF. “Scalp Cooling offers patients a way to maintain their dignity, self-esteem, and sense of empowerment, offering an alternative to one of the most dreaded side effects of chemotherapy,” Dr. Tauber adds.

To learn more about the DigniCap® scalp cooling system please visit www.DigniCap.com.

About Dignitana AB

Dignitana is a Swedish public company, based in Lund, and manufacturer of the patented medical scalp cooling device DigniCap®. Dignitana is

continuously researching and developing new uses for DigniCap®. Dignitana AB is listed on the OMX Nasdaq First North stock exchange and has appointed Erik Penser Bankaktiebolag as Certified Advisor. For more information visit www.dignitana.com.

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