

PRESS RELEASE

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Researchers Gather at The Royal Marsden to Study the Latest Advances of Scalp-Cooling Therapies to Prevent Hair Loss in Chemotherapy Patients

~ Promising Clinical Trial Results of DigniCap™ System Offer Hope for Male and Female Patients ~

LONDON (September 27, 2012)—On Tuesday of this week the world-renowned Royal Marsden cancer centre, in conjunction with Dignitana, maker of the DigniCap™ scalp-cooling system, held a scientific study day focused on [*Advances in Scalp Cooling and Future Developments*](#). Scientists, physicians and cancer patients from around the world participated in the forum, which concluded that many of the latest scalp-cooling advances and therapies are successfully improving quality of life for both male and female cancer patients at risk for chemo-related hair loss.

The Royal Marsden NHS Foundation Trust is currently running an independent ongoing academic comparative clinical trial to test the efficacy of different technologies for prevention of hair loss and improved quality of life for breast cancer patients being treated with chemotherapy.

Tuesday's meeting was chaired by Professor Robert Leonard, MD FRCP FRCPEd, Professor of Cancer Studies and Chief of Service for Medical Oncology at Imperial College.

The demand for scalp cooling and preservation of hair loss remains a priority for chemotherapy patients, said Dr. Leonard. As patient numbers and awareness continues to grow, this solution will be integrated into the healthcare process and offered to all eligible patients, both women and men.

“There is a strong case for pooling data in order to better understand the benefits and shortcomings of scalp cooling and finally, and we need better science to understand what the target effect of cooling is.”

At the meeting, clinical results of the DigniCap system were presented from clinical evaluations of well over 1000 patients in Japan, Germany, Scandinavia and the U.S. According to Dignitana research, eight out of ten women in Europe and Asia who used the company's cap cooling system during chemotherapy retained their hair.

In addition to the presentation of the international results, Kevin Saltmarsh, Lead Chemotherapy Nurse, Kings College Hospital in London, presented results from an ongoing investigation of the efficacy of scalp cooling in patients from various ethnic backgrounds with a hair quality different from that of Caucasian patients. **The available results show that scalp cooling is as effective in African patients as in Caucasian patients.**

“We are excited that The Royal Marsden has put such important focus on these new advances in scalp cooling,” said Martin Waleij, CEO Dignitana. “Results announced here this week, further confirm what clinical trials at leading medical centers around the world have shown, that the DigniCap system offers cancer patients a viable alternative to the emotionally devastating hair loss associated with chemotherapy treatments for both women and men.”

Further clinical results from investigations of the efficacy of scalp cooling with the DigniCap system will be presented at medical conferences and in publications throughout 2013.

Results from the first U.S. based feasibility clinical trial for the DigniCap system will be presented in December at the 2012 San Antonio Breast Cancer Symposium by Dr. Hope Rugo, Professor of Medicine and Director, Breast Oncology and Clinical Trials Education at the UCSF Helen Diller Family Comprehensive Cancer Center. Dr. Rugo is currently principal investigator for DigniCap system clinical trials in the U.S. Her research and clinical focus centers on breast cancer.

At the Royal Marsden meeting, Dr. Rugo discussed the hypothetically increased risk for scalp metastases in patients given chemotherapy together with scalp cooling. She concluded that scalp cooling has not been shown to increase the very low baseline incidence of scalp metastases. Therefore scalp cooling can be safely used with breast cancer patients receiving chemotherapy known to cause hair loss.

“We have performed a detailed review of the published data regarding scalp metastasis in patients with breast cancer using scalp cooling,” said Dr. Rugo, “and we see no evidence to suggest that incidence of this very rare event is increased by cooling. We are encouraged by these findings and excited both to present our robust pilot data this December, and to start the first multi-center carefully monitored study of scalp cooling in the U.S.”

Dr Tanveer Baig, Psychiatrist, Royal Marsden Hospital, presented on the psychological impact of hair loss, citing findings that show increased tolerance for chemotherapy and side effects when hair loss is reduced. Dr. Baig cited studies that indicated hair loss was the symptom associated with the most distress two months after surgery for chemotherapy patients, and was considered the most burdensome by 88 percent. Eight percent said they had considered refusing the treatment because of expected hair loss. “I lost very little hair and even my hairdresser couldn’t believe I was having chemotherapy,” said cancer patient Charlotte Reeves, who gave her personal testimonial at the Royal Marsden gathering. “Keeping my hair ... really helped me psychologically, so that I didn’t look physically unwell. I even managed to carry on working part time during my chemotherapy. One year on and my hair is nearly back to normal.”

About Dignitana AB (publ)

Dignitana AB, a Swedish medical device company, listed on the OMX Nasdaq First North Stockholm, focused on the patented invention DigniCap™ system, a medical device for preventing hair-loss in chemotherapy patients and for technologies within the area of medical cooling. or more information visit

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