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FDA APPROVES MULTI-CENTER PIVOTAL TRIAL OF NEW TREATMENT FOR CHEMOTHERAPY-RELATED HAIR LOSS

DigniCap® Scalp Cooling System Available at Leading U.S. Medical Centers

NEW YORK/SAN FRANCISCO, JUNE 5, 2013—Dignitana, a world leader in medical scalp-cooling technology, announced today that it has received U.S. Food and Drug Administration (FDA) approval for its Investigational Device Exemption (IDE) application and is now free to initiate a highly anticipated multi-center, pivotal trial of the patented DigniCap® System. The trial is the second and final phase of study in the United States and paves the way for FDA market approval of the scalp-cooling device, which is already widely used overseas.

Clinical trials will be conducted with 110 patients at prestigious major medical centers in the U.S. including University of California San Francisco, where the trial will be led by Principal Investigator Hope S. Rugo, MD, and Wake Forest Baptist Medical Center, led by Principal Investigator Susan Melin, MD. Several additional sites for the trial, including Medical Centers in New York City, will open throughout the summer.

"The FDA approval to proceed with this pivotal trial gives us an opportunity to gather additional data from clinical studies to evaluate the DigniCap System and seek final FDA clearance. We are excited to get this study underway and to make the treatment available to U.S. patients." said Martin Waleij, Chief Executive Officer for Dignitana.

To participate in the trial patients must be 18 years of age and have a documented diagnosis of stage I or II breast cancer, and must plan to complete chemotherapy within six months using standard chemotherapy regimens stipulated in the trial protocol.

"Breast cancer is the most common cancer diagnosis in women in the United States, and treatment has resulted in remarkable improvements with the majority of women surviving their disease," says 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. "Most women receive treatment in addition to surgery, almost always including chemotherapy. Hair loss is an inevitable side effect caused by this life-saving treatment, and for many women this is the most emotionally distressing and disturbing impact from their diagnosis. A short course of chemotherapy results in total hair loss taking many months to grow back."

"Devices that can reduce hair loss have the potential to have a significant impact on patient's quality of life, and this study is the first of its kind in the United States," Dr. Rugo adds. "Our goal is to provide data supporting approval of a device preventing hair loss, so that it is broadly accessible for use."

UCSF and Wake Forest previously conducted a pilot study using the DigniCap System in 20 women with early stage breast cancer. Dr. Rugo notes that the treatment was successful in the majority of women and well tolerated, laying the groundwork for this pivotal and larger trial.

"Wake Forest Baptist is excited to be a part of the upcoming trial to further test the DigniCap for breast cancer patients," said Susan A. Melin, MD, associate professor of hematology/oncology. "Being able to safely prevent chemotherapy-induced hair loss may relieve patients of some of the emotional stress they are already going through."

The state-of-the-art DigniCap® System being tested in this study features a tight-fitting silicone cap that is placed directly on the head, and an outer neoprene cap that insulates and secures the inner one. Both are connected to a cooling and control unit with touch screen controls. A patented coolant circulates throughout the inner silicone layer, and the cap is designed to deliver consistent cooling to all areas of the scalp. DigniCap is the only system to offer scalp-cooling above freezing with patented, built-in temperature sensors and a precision cooling mechanism that allows for gradual and highly tolerable scalp temperature fluxuations.

When a cap is applied to the head, the temperature of the scalp is lowered and blood vessels surrounding the hair roots contract, resulting in a significant reduction of cytotoxins to the follicle. Reduced blood flow leaves a smaller amount of chemotherapy available for uptake in the cells, and the decreased temperature results in less absorption of and reduced effects from chemotherapy. These factors together reduce the risk of hair loss.

Clinical trials done in Europe and Asia show that eight out of ten women who used the DigniCap® System during chemotherapy retained their hair. Additional trials at leading medical centers around the world have proven the system to be a viable alternative for both women and men of diverse ethnicities.

“The DigniCap® System has been extremely well received in clinical trials at leading medical centers around the world,” Waleij says, “and we are pleased to be able to work now with the U.S. regulatory system and these prestigious medical centers to provide this highly tolerable, safe and effective therapy for cancer patients in the United States.”

Historically, cooling systems and cold caps have not been used in the United States because of concerns that the scalp cooling could allow cancer cells to hide in the scalp. UCSF’s Hope Rugo reports that “the incidence of scalp metastases in breast cancer is extremely low and in a large review of published data on scalp cooling systems, scalp metastases were not increased. We are carefully following patients using these systems in several clinical trials.”

For more information about participating in one of The DigniCap® System clinical trials, please visit www.Dignitana.com.

UCSF is a leading university dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care.

Dignitana AB (publ) is a Swedish medical device company listed on the OMX NASDAQ First North Stockholm is a world leader in technologies within the area of medical cooling. For more information about Dignitana and the DigniCap® System, please visit <http://www.dignitana.com>.

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