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DIGNITANA

Media Contact – US

Caren Browning
King + Company
00 1 212 561 7464
caren.Browning@kingcompr.com

Corporate Contact – Sweden

Johan Ericsson, CEO
Dignitana AB
+46 46 163092
johan.ericsson@dignitana.se

FDA EXPANDS DIGNICAP CLEARANCE IN U.S. TO SOLID TUMOR CANCERS MEDICAL DEVICE NOW FDA CLEARED FOR BREAST, PROSTATE, OVARIAN, AND OTHER SOLID TUMOR CANCERS

Scalp Cooling Option Can Reduce Fear of Chemotherapy-Related Hair Loss for Many Men and Women

Lund, Sweden – July 3, 2017— Dignitana AB, a world leader in medical scalp cooling technology and manufacturer of the DigniCap® Scalp Cooling System, announced today that it has [received clearance](#) from the U.S. Food and Drug Administration (FDA) to expand use of its medical device to patients in the United States receiving chemotherapy for solid tumor cancers. Originally cleared in December 2015 by the FDA as the first scalp cooling device for use in women with breast cancer, the clinically-tested automated scalp cooling device is administered in medical facilities as patients receive their chemotherapy infusion.

Although breast cancer is the most common malignancy in women worldwide with 255,000 new incidences of the disease each year in the U.S., this year alone, nearly 800,000 new cases of solid tumor cancers are diagnosed in the U.S. annually, with more than six million patients receiving diagnoses worldwide (cancer.org).

With expanded FDA clearance, oncologists and surgeons treating cancer patients with solid tumors such as those associated with breast, prostate, ovarian, uterine, lung and other tissues will be able to consider scalp cooling treatments for patients receiving chemotherapy infusions.

“Scalp cooling is recognized around the world as a safe and effective therapeutic solution to one of the most traumatic side effects of chemotherapy,” said **Johan Ericsson, Chief Executive Officer of Dignitana AB**. “Dignitana takes great pride in our ability to lead the way and remain at the cutting edge of technological developments that provide a transformative quality of life experience for people coping with a cancer diagnosis. This FDA decision allows us to help even more patients in the U.S. as they navigate life with the disease.”

As reported in the [Journal of the American Medical Association \(JAMA\)](#) earlier this year, 66.3% of patients with early-stage breast cancer using the DigniCap® Scalp Cooling System in multi-center clinical trials kept at least 50% of their hair. With expanded FDA clearance, Dignitana and its [cancer center partners](#) can now make treatments available on a considerably larger scale.

“Dignitana’s mission remains focused on providing cancer patients with the best possible care and outcomes as they undergo treatment,” said **William Cronin, Chief Executive Officer of Dignitana, Inc.** “As the first in the U.S. to provide an FDA-cleared solution to prevent chemotherapy induced hair loss, we’ve seen firsthand the tremendous impact this new technology can have on patient wellbeing. Together with our medical center partners we are working to lessen the emotional burden that so many patients have faced until now. We hope this expanded FDA clearance will be welcome news for thousands of Americans diagnosed with solid tumors each year.”

“With breast cancer patients, we have seen positive results with scalp cooling treatments, although success is dependent on the type and dose of chemotherapy,” said **Dr. Hope Rugo, Professor of Medicine, Director, Breast Oncology and Clinical Trials Education at UC San Francisco**, a breast cancer specialist with the UCSF Helen Diller Family Comprehensive Cancer Center, and principal investigator for the clinical trial reported in JAMA. “Patients with other cancers using similar chemotherapy treatments may also benefit from scalp cooling to preserve their hair, and scalp cooling is used world-wide to prevent hair loss for a number of cancers, including gynecologic cancers and cancer of the prostate as well as

others. We are confident that scalp cooling is safe, and we're pleased that the FDA has expanded clearance so that scalp cooling can be used by both women and men who have other types of solid tumors."

"We know that many patients struggle as they experience chemotherapy-induced hair loss associated with breast and other solid tumors" said **Mario Lacouture, MD, Director of the Oncodermatology Program at Memorial Sloan Kettering Cancer Center**. "Scalp cooling is clinically proven and can be an important component in selected chemotherapy regimens in various tumor types, in patients for whom preventing hair loss is important for their well-being."

The DigniCap[®] Scalp Cooling System features a 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. A liquid coolant circulates throughout the silicone cap, delivering consistent and controlled cooling to all areas of the scalp. Once the cap is fitted to the head, the temperature of the scalp is lowered to be just above freezing temperature, 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 minimize the hair loss that is a side effect of many chemotherapy agents.

DigniCap[®] is [available](#) at more than 80 clinical sites across 21 states in the United States, helping hundreds of patients per month minimize chemotherapy-induced hair loss.

For more information, please visit the FDA website:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm565599.htm>

For press images: <https://dignicap.com/product-images>

About Dignitana AB (publ)

Dignitana is a Swedish public company based in Lund and manufacturer of the medical cooling device DigniCap[®]. Dignitana AB is listed on Nasdaq First North Stockholm and has appointed Erik Penser Bank as Certified Adviser. Headquartered in Dallas, Texas, **Dignitana, Inc.** is the U.S. subsidiary of Dignitana AB. For more information visit www.dignitana.se

About The DigniCap[®] Scalp Cooling System

DigniCap[®] is a patented scalp cooling system that offers cancer patients the ability to keep their hair during chemotherapy. DigniCap[®] provides continuous cooling with high efficacy, safety and acceptable patient comfort. www.dignicap.com

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This information is information that Dignitana AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, by the above contact, for publication at 21:15 (CET), 3 July 2017.

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