Dignitana AB Receives CE Marking for Next Generation DigniCap Delta to Reduce Hair Loss from Chemotherapy

**Dignitana AB (publ),** manufacturer of The DigniCap® Scalp Cooling System, today announced receiving CE Marking approval for European sales of **DigniCap Delta,** the next generation scalp cooling device. An advanced and redesigned model of the 2015 FDA-cleared DigniCap Scalp Cooling System, DigniCap Delta features a new single patient use cap system consisting of a flexible Cooling Wrap and an adjustable Thermal Cap to optimize scalp cooling outcomes and ease-of-use for patients and nurses. The streamlined **DigniCap Delta** is 54 percent smaller than the current model and the intuitive interface provides up to 80 percent reduction in nursing time per patient infusion versus the existing device.

It is anticipated that that the first customers will receive DigniCap Delta in early May. The new device will then be available in the United States once FDA clearance is received.

“DigniCap Delta changes everything about the way scalp cooling is done today. Health care providers want to improve the clinical process, reduce nursing intervention and optimize patient outcomes – and this device does all three,” said William Cronin, CEO of Dignitana. “We are thrilled to receive the CE Marking which provides a critical pathway for Dignitana’s growth. This approval not only means that we can now initiate sales of DigniCap Delta in Europe, but it also opens the door to introduce the new device in Australia and several other countries.”

DigniCap is used by patients with solid tumor cancers to treat chemotherapy-induced alopecia. With innovative technology incorporating solid-state cooling for precise temperature control and an adjustable cap system, the new DigniCap Delta device provides significant improvements over scalp cooling systems currently on the market.

The **Conformité Européenne** (CE) Marking is required for medical device sales in all 28 member states of the European Union, as well as Iceland, Liechtenstein, Norway, and Switzerland. The CE Mark also has Agreements on Mutual Recognition of Conformity Assessment with Australia, Israel, New Zealand, and Turkey.

The National Comprehensive Cancer Network in the U.S. also recently announced an update to their category 2A recommendations to “Consider scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving chemotherapy.” This recognition provides further evidence that the adoption of scalp cooling as a standard of care is growing around the world.

Hailed internationally as a life-changing medical advancement for cancer patients, The DigniCap Scalp Cooling System was invented in 1999 by a Swedish Oncology nurse and has been available in Europe since 2001. DigniCap was the first scalp cooling system to be cleared by the FDA in 2015 for use by breast cancer patients and the first to receive FDA clearance for use by patients with solid tumor cancers in July 2017. Data from clinical studies around the world, including the pivotal trial for FDA clearance, have illustrated that DigniCap provides clinically superior scalp cooling.

*This is information that Dignitana AB (publ) 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 08:30 (CET), on 27 March 2019.*

**About Dignitana AB (publ)**
Dignitana AB is the world leader in clinically superior scalp cooling technology. The company produces The DigniCap Scalp Cooling System, a patented medical cooling device that offers cancer patients the ability to minimize hair loss during
chemotherapy. FDA cleared since 2015, DigniCap provides continuous cooling with high efficacy, safety and acceptable patient comfort. Dignitana AB is listed on Nasdaq First North Stockholm in Sweden with headquarters in Lund, Sweden and operations based in Dallas, Texas in the United States. Company subsidiaries are Dignitana, Inc. in the United States and Dignitana S.r.l. in Italy. Erik Penser Bank is Certified Adviser. Visit www.dignitana.se or www.dignicap.com or view the DigniCap Delta video here.

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