

Elekta Unity, world's first high field MR-linac, receives FDA 510(k) clearance New radiation therapy system will now be implemented clinically in U.S., ushering in a transformation in precision and personalized cancer treatment

STOCKHOLM – Elekta (EKTA-B.ST) today announced that its Elekta Unity magnetic resonance radiation therapy (MR/RT) system has received 510(k) premarket notification from the U.S. Food and Drug Administration, clearing the technology for commercial sales and clinical use in the United States.

"Since receiving CE mark in June 2018, Elekta Unity has been transforming the care of cancer patients in Europe, and we are excited that this cutting-edge technology is now commercially available to U.S. patients," said Richard Hausmann, President and CEO, Elekta. "With Elekta Unity, it is now feasible to develop personalized, precision radiation therapy regimens that are optimized for safety and efficacy and make radiation therapy a viable treatment option for more patients. We thank our international MR-linac consortium members and our MR technology partner, Philips, as well as our dedicated employees for helping us to achieve this milestone, which is a critical one for Elekta and the patients who may benefit from this cutting-edge technology."

Unity has the potential to transform how clinicians treat cancer by enabling the delivery of the radiation dose while simultaneously visualizing the tumor and surrounding healthy tissue with high-quality MR images. Unity also integrates advanced tools that allow clinicians to adapt the patient's treatment to this current anatomical information within a treatment session.

"Unity is a tremendous leap forward in our ability to tailor radiation therapy to each patient's tumor and anatomy and to adapt treatment in real time as the tumor changes shape and position relative to organs at risk," said Christopher Schultz, MD, FASTRO FACR, Medical College of Wisconsin, Bernard and Miriam Peck Family Professor and Chairman of the Department of Radiation Oncology, at the Froedtert & MCW Cancer Network and Chair of the Elekta MR-linac Consortium. "I believe this enabling technology will fundamentally transform how radiation therapy regimens are developed, implemented and adapted to achieve optimal outcomes for our patients. We are excited to offer Unity to our patients and are proud of our contributions to making this technology a clinical reality."

## **About Elekta Unity**

Elekta Unity, the first high field MR/RT system, combines high-field 1.5 Tesla MR imaging, precision radiation therapy and intelligent software, allowing clinicians to see what they treat in real time. Elekta Unity addresses a critical unmet need in cancer therapy. Now clinicians can confidently see and track the tumor and difficult-to-visualize soft tissue anatomies during treatment and adapt the treatment to optimize therapy. This enables personalized therapy for each patient and every treatment session.

To learn more, visit elekta.com/Unity.

This is information that Elekta AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication at 08:45 CET on December 5, 2018. (REGMAR)



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## **About Elekta**

Elekta is proud to be the leading innovator of equipment and software used to improve, prolong and save the lives of people with cancer and brain disorders. Our advanced, effective solutions are created in collaboration with customers, and more than 6,000 hospitals worldwide rely on Elekta technology. Our treatment solutions and oncology informatics portfolios are designed to enhance the delivery of radiation therapy, radiosurgery and brachytherapy, and to drive cost efficiency in clinical workflows. Elekta employs 3,700 people around the world. Headquartered in Stockholm, Sweden, Elekta is listed on NASDAQ Stockholm. www.elekta.com