Press release: November 1, 2018

Elekta Unity MR-linac featured in 11 abstracts at ASTRO 2018
Diverse studies demonstrate transformative potential for MR/RT in various cancer indications to deliver radiation to a variety of tumor types while protecting nearby tissues and organs

STOCKHOLM – Elekta (EKTA-B.ST) today announced that its Elekta Unity magnetic resonance radiation therapy (MR/RT) system was featured in 11 abstracts at the American Society for Radiation Oncology (ASTRO) Annual Meeting, which took place October 21-24 in San Antonio, Texas. Elekta Unity, which received CE Mark in June 2018 and currently pending U.S. FDA 510(k) premarket clearance, is the first high-field MR/RT system that allows clinicians to see and track difficult-to-visualize soft tissue anatomies in real-time during radiation dosing.

“As a transformative approach to cancer care, clinical implementation of MRgRT requires not only novel hardware and software systems, but also needs clinical evidence to enable treatment that is optimized for specific tumor types and to address the unique anatomy and tumor biology of each patient,” said X. Allen Li, PhD, Chief Physicist, Department of Radiation Oncology at Froedtert & the Medical College of Wisconsin Clinical Cancer Center.
“The MR-linac studies presented at ASTRO add to the solid foundation of data demonstrating how MRgRT can address some of the historic challenges to balancing effective delivery of radiation to tumors while protecting nearby tissues and organs at risk. This has the potential to improve outcomes for cancer patients.”

The data presented at ASTRO reflect the broad array of studies that the Elekta MR-linac Consortium is conducting to generate the clinical evidence that will support optimum use of MR/RT in diverse clinical settings. The Consortium is a collaborative industrial-academic partnership that Elekta founded with seven centers and its technology partner, Philips, in 2012 to provide an evidence-based introduction of Elekta MR-linac to the medical community, and to support the advancement of the technology.

In addition to the abstracts presented at ASTRO, the first clinical centers in Europe presented their experience on online adaptation treatments with Elekta Unity at the Elekta User Meeting held in conjunction with the Annual Meeting. These presentations described how European centers that have clinically implemented Unity are adapting each treatment to daily anatomies while the patient is on the treatment table. These adapted treatment sessions can be completed in 30 – 45 minutes.

Key findings presented by the Consortium at ASTRO included:

- *Inter- and intra-patient peristaltic motion assessed with Cine-MRI*[1]
  This study evaluated the motion of organs due to peristalsis using 2D cine-MRI images acquired during simulation of radiation therapy. A total of 33 cine MRI sets were acquired and select fractions for 10 patients with pancreatic cancer were analyzed for various organs, including gall bladder and liver. Gall bladder motion results from both peristalsis and breathing, while liver motion is primarily due to breathing. As a result, subtracting liver motion from gall bladder motion allows the impact of peristalsis on organ motion to be assessed. Results show that peristalsis can result in abdominal organ motion of up to 10 mm, and that the pattern of this motion is complex compared with motion due to breathing. Importantly, results show that peristalsis-related motion

can be irregular and persistent throughout radiation therapy imaging and delivery. This underscores the need to manage peristaltic motion in high-precision radiation therapy for abdominal tumors.

- *Early experience of magnetic resonance sequence evaluation using an MR-linac system*[2]
  This study focused on optimizing the selection of MR sequences following volunteer imaging on the Elekta MR-linac imaging platform. Eighteen non-patient volunteers underwent 21 prospective MR-imaging sessions to one of four anatomical regions: male pelvis (n=7), female pelvis (n=3), thorax-chest wall/breast (n=5), abdomen (n=3). Volunteers attended 1-3 imaging sessions that included an mDixon, and a combination of 2D, 3D, T1w and T2w sequences. On average, volunteers underwent 10 sequences (range 5-20), with a maximum scan time of approximately one hour. Multiple panels comprising clinical oncologists and fellows specializing in particular anatomies/tumor types evaluated the images, and the visibility of relevant organs-at-risk was used to determine image quality on a 4-point Likert scale of very clear, clear, unclear and not visible. Results show that the majority of observers preferred T2-weighted 3D sequences. The breast team was the only group to prefer T1-weighted imaging; and only the abdominal group preferred triggered image acquisitions. This study highlights the importance of optimizing the type of MR sequence used in specific tumor types.

- *Characterizing interfraction variation of separation between pancreas and duodenum during radiation therapy of pancreatic cancer for online adaptive replanning*[3]
  This study was designed to quantitatively characterize inter-fractional variation of the relative motion between the pancreatic head and the duodenum during radiation therapy for the treatment of pancreatic cancer. Daily CTs were acquired during routine image-guided radiation therapy for 33 patients with pancreas head tumors treated with chemotherapy in combination with radiation therapy (50.4 Gy in 28 daily fractions). A total of 177 CTs were included in the analysis. Results show that the inter-fraction variation in the maximum separation between duodenum and pancreatic head for any patient, as measured by modified Hausdorff distance (HD), was 1.9±0.6 cm, and the average HD variation for all patients was 0.9±0.3 cm; the largest HD was 2.4 cm for all the fractions. Overlap between the pancreatic head and duodenum was quantified by uniformly expanding the pancreatic head contour by 20 mm and measuring the volume overlap (VO) between the pancreatic-head shell and the duodenum relative to the duodenal volume. The minimum VO between the pancreatic head and duodenum for any patient was 11.4±4.7% and the average VO for all patients was 25.2±6.4%. For a fraction with HD = 1.7 cm and VO =37%, online re-planning resulted in a reduction in the duodenal volume receiving 50 Gy from 63% to 19%. Such a reduction would allow substantial dose escalation to the target for the fraction with online adaptive radiation therapy. In 40% of fractions in which HD ≥ 1.0 cm, online adaptive radiation therapy may be used to safely escalate the dose to the target by taking advantage of the large separation or small overlap.

“The data presented at ASTRO further validate Elekta’s strategy of collaborating with global leaders in cancer care to usher radiation therapy into the era of fully personalized precision radiation medicine,” said Richard Hausmann, President and CEO, Elekta. “Robust clinical data

that demonstrate how to leverage the innovative features of our MR-linac system are essential for realizing the tremendous potential of MR/RT as a wholly new approach to radiation therapy. We continue to be grateful for the contributions that our clinical collaborators have made to the development of our MR-linac system and to ensuring that this innovation yields real benefits for cancer patients."

To learn more, visit elekta.com/Unity.

**Elekta Unity is pending 510(k) premarket clearance and not available for commercial distribution or sale in the U.S.*

[1] Mostafaei, F., Tai, A., Liu, Q., Paulson, E.S., Hall, W.A., Erickson, B.A., Li, A. *International Journal of Radiation Oncology*Biology*Physics. 2018 Nov 1; 102(3):S130.* DOI: 10.1016/j.ijrobp.2018.06.322

[2] Eccles, C.L., Hunt, A., McNair, H., Herbert, T., Tree, A., Kirby, A., Bhide, S., Lalondrelle, S., Pathmanathan, A., White, I., Newbold, K., Aitken, K., McDonald, F., Mandeville, H.C., Lavan, N., Nill, S., Hafeez, S., Harrington, K., Oelfke, U., Huddart, R.A. *International Journal of Radiation Oncology*Biology*Physics. 2018 Nov 1; 102(3):S130-S131.* DOI: 10.1016/j.ijrobp.2018.06.323

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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