Press release: July 23, 2025

Elekta receives U.S. FDA 510(k) clearance for its Gamma Knife radiosurgery system to treat patients with refractory, drug-resistant mesial temporal lobe epilepsy

New indication expands treatment options for neurosurgeons managing complex epilepsy cases

ATLANTA – Elekta (EKTA-B.ST) today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to include refractory, intractable mesial temporal lobe epilepsy (MTLE) in adults among its indications for use with the company's Leksell Gamma Knife radiosurgery system. Intractable epilepsy, also known as drug-resistant epilepsy, is a form of the disease in which a person's seizures cannot be controlled with medication. Gamma Knife surgery treats refractory, drug-resistant MTLE by precisely focusing 192 beams of gamma radiation to target and disrupt the exact region of the brain responsible for epileptic seizures, potentially reducing frequency or eliminating them without opening the skull.

Gamma Knife is a dedicated intracranial system designed exclusively for brain radiosurgery. Developed by Swedish neurosurgeon, Prof. Lars Leksell, its original purpose was to treat functional indications – such as intractable epilepsy – without the need for open brain surgery. Since 1968, it has been used globally to treat a range of functional indications including essential tremor, trigeminal neuralgia and intractable epilepsy – offering nearly two million patients a non-invasive alternative that spares healthy brain tissue and critical structures.

"For years, many of Elekta's neuroscience clinical partners have used Gamma Knife to treat patients with epilepsy, often with remarkable outcomes," said Caroline Leksell Cooke, Senior Vice President and Head of Neuro Solutions at Elekta. "With this new clearance, U.S. providers can now offer patients a non-invasive, precision treatment – an important step forward in improving patient outcomes while optimizing resource utilization."

Learn more about stereotactic radiosurgery with Gamma Knife at elekta.com/gammaknife.

Leksell Gamma Knife has U.S. FDA 510(k) clearance for the new indication of "drug resistant epilepsy" with limited global availability.

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About Elekta
As a leader in precision radiation therapy, Elekta is committed to ensuring every patient has access to the best cancer care possible. We openly collaborate with customers to advance sustainable, outcome-driven and cost-efficient solutions to meet evolving patient needs, improve

lives and bring hope to everyone dealing with cancer. To us, it's personal, and our global team of 4,500 employees combine passion, science, and imagination to profoundly change cancer care. We don’t just build technology, we build hope. Elekta is headquartered in Stockholm, Sweden, with offices in more than 40 countries and listed on Nasdaq Stockholm. For more information, visit elekta.com.