



PRESS RELEASE

Stockholm, 28 October 2003

Images available – see below!

ELEKTA RECEIVES FDA CLEARANCE FOR ELEKTA SYNERGY™

The revolutionary new radiotherapy system from Elekta is first to combine x-ray volume imaging and treatment in a single platform

On Monday the 27 October, the U.S. Food and Drug Administration (FDA), granted 510(k) pre-market clearance to the Elekta Synergy™ System from Elekta. This means that Elekta can now market and sell the system also in the U.S. In Europe, Elekta Synergy™ is already marketed, following CE marking in July 2003.

In research and development over the last five years, this new radiotherapy treatment platform directly addresses the two most persistent and significant problems in modern radiation therapy: internal organ motion and errors in patient set-up.

Elekta was the first vendor to start research on image-guided radiation therapy, the first to have systems in clinical use, and the first to bring these solutions to the market.

“With the introduction of Elekta Synergy™, Elekta is leading the efforts to increase the precision of radiotherapy delivery by limiting or even eliminating the impact of the patient’s internal organ motion and how the patient is set up for treatment from day to day”, says Peter J. Gaccione, vice president Oncology Sales and Service Operations for Elekta North America.

Elekta Synergy™ does this by using innovative x-ray volume imaging technology that is integrated directly onto the treatment system itself. This means that routine pre-treatment imaging of a tumor can now be performed immediately prior to treatment, decreasing the risk that a tumor or internal organs will change position. In addition, since the patient doesn’t have to be moved from an imaging device (e.g. MR, CT) to the radiotherapy treatment machine, the problem of errors from patient re-setup are eliminated.

The first use of this new class of Image Guided Radiation Therapy (IGRT) technology took place at the Netherlands Cancer Institute (NKI) in July 2003, when three cancer patients were treated using the Elekta Synergy™ system. In addition to NKI, three other leading cancer clinics in Great Britain, Canada and USA have research installations of Elekta Synergy™.

Clinical data presented both at the recent ASTRO annual meeting in the U.S. and the European ESTRO meeting, demonstrate the enormous potential for the new Elekta Synergy™ system to significantly advance radiotherapy treatment for cancer patients.

It has been shown that by combining an X-ray volume imaging system and radiotherapy equipment (a medical accelerator) to provide ‘real time’ images of the tumour during treatment, the image quality and treatment accuracy is significantly improved. (ref: 1,2)



Volker Stieber, Elekta's Executive Vice President – Technology Development & Operations, acknowledged the aptness of the new product's name, "Synergy is defined as two or more entities working together, wherein the sum is greater than each individual's contribution. Elekta Synergy™ adds dedicated imaging technology to a proven treatment platform, creating a system that is truly more than the sum of its parts."

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Notes to editors:

- For further information regarding Elekta Synergy™ and other Elekta products, please visit www.elekta.com
- Images of Elekta Synergy™ can be accessed at the following website address: www.elekta.com/investors

About Elekta:

Elekta is a world-leading supplier of advanced and innovative radiation oncology and neurosurgery solutions and services for precise treatment of cancer and brain disorders. Elekta's solutions are clinically effective, cost efficient and gentle to the patient.

References:

1. Oldham M, et al. Online volumetric CT-guided radiation therapy. Abstract 101. American Society for Therapeutic Radiology and Oncology Annual Meeting, October 2003.
2. Letourneau D, et al. Implementation of an on-board kilovoltage cone-beam CT imaging system for clinical applications. Abstract 102. American Society for Therapeutic Radiology and Oncology Annual Meeting 2003.