Elekta receives 510(k) clearance for Venezia, an image-guided brachytherapy applicator for treating advanced-stage gynecological cancers

Provides clinicians with improved access to stage IIA, IIB and IVA tumors in the cervix, parametrium and vaginal extensions

STOCKHOLM, February 2, 2017 – Elekta (EKTA-B.ST) today announced its Venezia™ applicator for gynecological brachytherapy has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the treatment of advanced-stage cervical cancer. Venezia received CE Mark approval in November 2016.

Cervical cancer is the fourth most common cancer in women and results in 266,000 deaths globally each year. With advanced cervical cancer, the tumor often extends outside of the cervix, involving the parametrium, vagina and perineum. The standard of care for locally advanced cervical cancer is a combination of chemotherapy and radiation. The radiation component of this approach includes external beam radiation therapy (EBRT) with a brachytherapy boost.

Data from a published clinical study demonstrated that cervical cancer patients receiving a brachytherapy boost following EBRT had 12 percent better overall survival at four years compared with patients receiving EBRT alone.\(^1\) Other studies have shown that the use of 3D image-guided brachytherapy using interstitial needles that expand the treatment area and conform to the shape of the tumor is associated with improved clinical outcomes, especially for patients with larger tumors.\(^2\)\(^-\)\(^4\) Despite these findings, the use of interstitial brachytherapy in patients with tumors that extend outside of the cervix may be underutilized due to the limited reach of existing applicators and the complexity of precisely targeting tumor tissue. Venezia employs a unique design that facilitates pre-defined and consistent needle placement for every procedure, and allows clinicians to access difficult to reach tumors that extend outside of the cervix.

“There is overwhelming clinical evidence that modern image-guided brachytherapy is an effective treatment modality for cervical cancer. Advanced stage disease, however, often requires an interstitial technique due to a less than complete response to chemoradiation therapy,” says Phillip M. Devlin, MD, FACP, FASTRO, FFRRCSI (Hon), Chief Division of Brachytherapy, Brigham and Women’s Hospital. “The surgical brachytherapy skill set to do this, however, is only available in the minority of radiation oncology programs around the world. Modified intracavitary applicators that allow better interstitial coverage and require less technical skill and training have the potential to increase access of this needed therapy to more women.”

“To develop Venezia, we collaborated with physicians and physicists at the cutting edge of 3D image-guided adaptive brachytherapy,” says Maarten ter Mors, Vice President Brachytherapy Portfolio at Elekta. “Our mutual goal was to make this potentially lifesaving treatment available to more patients. Although we initially focused on advanced-stage disease, Venezia has evolved into an intuitive tool suitable for treating a wide range of gynecological malignancies. We believe it has the potential to positively impact the way gynecological cancers are treated.”

Recognizing that successful interstitial brachytherapy for cervical cancer requires more than an innovative applicator, Elekta provides peer-to-peer workshops that provide
caregivers with the information they need to use Venezia for optimum benefit through the company’s BrachyAcademy.

For more information about Venezia, please visit www.elekta.com/venezia.

Advanced Gynecological Applicator Venezia™ is CE-approved and available for sales in the USA, but is not available in all markets.

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For further information, please contact:
Gert van Santen, Group Vice President Corporate Communications, Elekta AB
Tel: +31 653 561 242, e-mail: gert.vansanten@elekta.com
Time zone: CET: Central European Time

Raven Canzeri, Global Public Relations Manager, Elekta
Tel: +1 770-670-2524, e-mail: raven.canzeri@elekta.com
Time zone: ET: Eastern Time

About Elekta
Elekta is a human care company pioneering significant innovations and clinical solutions for treating cancer and brain disorders. The company develops sophisticated, state-of-the-art tools and treatment planning systems for radiation therapy, radiosurgery and brachytherapy, as well as workflow enhancing software systems across the spectrum of cancer care. Stretching the boundaries of science and technology, providing intelligent and resource-efficient solutions that offer confidence to both health care providers and patients, Elekta aims to improve, prolong and even save patient lives.

Today, Elekta solutions in oncology and neurosurgery are used in over 6,000 hospitals worldwide. Elekta employs around 3,600 employees globally. The corporate headquarters is located in Stockholm, Sweden, and the company is listed on NASDAQ Stockholm. Website: www.elekta.com.

1 Han K et al. Int J Radiation Oncol Biol Phys 2013; 87:111-119.