Radiation Therapy System FDA-Cleared To Treat Early-Stage Breast Cancer

The MammoSite ML (multi-lumen) device offers more women the option of completing their radiation treatment in just five days

BEDFORD, Mass., Sept. 1 /PRNewswire-FirstCall/ -- Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced the U.S.

Food and Drug Administration (FDA) cleared the Company's 510K application for the MammoSite ML radiation therapy system. With its multi-lumen design, this new device gives radiation oncologists the ability to shape the radiation dose for typical cases and treat patients who are otherwise not appropriate candidates for traditional brachytherapy.

Hologic's MammoSite therapy system, first cleared by the FDA in 2002 as a single-lumen device, is the most widely used form of accelerated partial breast irradiation (APBI) in the United States. It has been used to treat more than 50,000 breast cancer patients in the U.S.

By employing the MammoSite system, the physician can deliver targeted radiation therapy directly to the area where cancer is most likely to recur,(i) allowing a full course of radiation to be delivered in just five days. Additionally, targeted therapy of the breast limits radiation exposure to normal, healthy tissue. This targeting helps minimize side effects such as skin discoloration and scarring, burning, fatigue, and damage to surrounding organs.

In 2008, approximately 240,000 cases of breast cancer were confirmed in the U.S. Fortunately, today more than half of breast cancers are diagnosed when the disease is still in its localized stage.(ii) Early detection allows breast cancer patients to choose breast conservation therapy, which preserves the breast by relying on tumor excision via lumpectomy, followed by radiation therapy, to reduce the likelihood of recurrence. According to the National

Institutes of Health, breast-conserving surgery plus radiation therapy is preferable to total mastectomy because it provides survival equivalence while preserving the breast.(iii)

The MammoSite systems are comprised of an inflatable balloon catheter in which a radioactive source is introduced for therapy delivery. The inflatable balloon is inserted into the surgical cavity remaining after removal of the tumor. This local placement of the balloon provides for therapeutic delivery of a five-day course of

radiation to the tissue most likely to contain residual cancerous cells following surgery, while reducing radiation exposure to adjacent healthy tissue. Using the MammoSite multi-lumen catheter, the radiation oncologist has the ability to shift the radiation dose to the areas that need it most and shift the dose away from areas that do not require it.

"An increasing number of surgeons, radiation oncologists, and patients are choosing the accelerated treatment available with MammoSite," said David Harding, senior vice president of Hologic's interventional breast solutions business. "Now, with MammoSite ML, five-day targeted radiation therapy is also available to women with early-stage tumors close to the skin or chest wall who may not have been good candidates for traditional balloon brachytherapy. This is another significant milestone for Hologic and our interventional breast solutions business. With FDA clearance of the MammoSite ML radiation therapy system, we are now able to provide surgeons and radiation oncologists with a device designed to both maximize patient comfort and enable greater physician flexibility in delivering targeted radiation therapy directly to the areas where breast cancers are most likely to recur."

Visit www.mammosite.com [1] for additional information.

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