Clinical Experience Updates with CivaSheet® Directional Brachytherapy in the Treatment of Sarcoma

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RESEARCH TRIANGLE PARK, N.C.  CivaTech Oncology®

Physicians report CivaSheet®, a unidirectional LDR brachytherapy implant, demonstrates up to three year local control in recurrent retroperitoneal sarcomas when implanted during surgical resection. The crude cumulative incidence of local recurrence (LR) is 26%. To date, 21 sarcoma patients have been implanted with CivaSheet at six medical centers. Sarcoma patients tolerate the implant well with no complications following surgery. None of the 21 patients (0/21) have demonstrated local recurrence. There were no reported incidences of acute or late radiation toxicity despite the surrounding organs at risk, including small bowel, ureter and kidneys. The directional source distribution allows for safe re-irradiation or adjuvant brachytherapy boost radiation therapy in patients who have had maximum EBRT dose.

A recent publication details a patient with more than 3 years follow up. This report demonstrates “CivaSheet was associated with durable local control and significant reduction in doses to OARs including bowel, rectum, and bladder.” Additionally, “the bioabsorbability, flexibility, and easy identification on CT imaging allow this device to treat tumors in irregularly shaped cavities such as the pelvic sidewall and retroperitoneum.” The uni-directional design protects healthy tissues allowing a targeted dose with no toxicity. The novel polymer encapsulation allows unprecedented dose uniformity. “Moreover, the directional nature of this device helps increase the therapeutic ratio by avoiding unnecessary irradiation of OARs.” Furthermore, “CivaSheet expands IORT capabilities in a resource independent manner.” Application of uni-directional, planar Pd-103 LDR brachytherapy technology is safe and easy and should be considered as a standard option to escalate dose to high risk margins after resection.

About CivaSheet®:

CivaSheet® is a flexible, implantable intra-operative radiation therapy (IORT) device (brachytherapy), which emits unidirectional radiation by integrating gold shielding into its polymer encapsulation. CivaSheet has broad FDA clearance to include sarcoma and many other malignancies. CivaSheet enables boost radiation therapy in patients who have otherwise received the maximum radiation dose.

Development of the CivaSheet and clinical studies are partially supported by the NIH, NCI and the NC Biotech Center.

About CivaTech® Oncology:

CivaTech Oncology’s products bring meaningful improvements to provide targeted personalized radiation therapy in more aggressive doses with higher tolerability. For more information, please visit www.civatechoncology.com.

ABOUT ASTRO
The American Society for Radiation Oncology (ASTRO) is the world’s largest radiation oncology society, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating
patients with radiation therapies. The Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three medical journals, *International Journal of Radiation Oncology • Biology • Physics, Practical Radiation Oncology* and *Advances in Radiation Oncology*; developed and maintains an extensive patient website, *RT Answers*; and created the nonprofit foundation *Radiation Oncology Institute*. To learn more about ASTRO, visit astro.org or RTanswers.org, sign up to receive our news and follow us on our blog, Facebook and Twitter.

This news release contains additional and/or updated information from the study author(s).

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Release Summary

- Directional, planar Pd-103 LDR brachytherapy has demonstrated up to 3-year recurrence-free survival in retroperitoneal sarcoma patients with focally positive microscopic margins.

For Clinical Study locations contact:

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