+MASS DEVICE

FDA clears biology-guided radiotherapy from RefleXion

By Sean Whooley | February 2, 2023

RefleXion Medical announced today that the FDA cleared its Scintix biology-guided radiotherapy treatment for cancer.

Hayward, California-based RefleXion designed the Scintix platform for use in treating both early- and late-stage cancers.

The company said Scintix is the first and only radiotherapy that allows each cancer's unique biology to autonomously determine how much radiation to deliver. This occurs on a second-by-second basis during the actual treatment delivery.

Clearance by the FDA expands the RefleXion X1 system into a dual-treatment modality platform. It can now treat patients with indicated solid tumors of any stage. Scintix tracks tumor motion from all types of movement, including expected motion from internal processes like breathing and digestion. X1 also features a state-of-the-art anatomic modality cleared by the FDA for solid tumors located anywhere in the body.

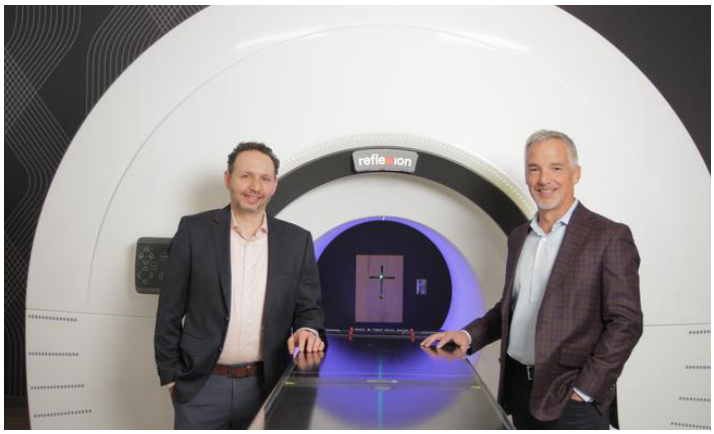
Dr. Terence Williams, chair of City of Hope's radiation oncology department, said Scintix "ushers in a new era of external-beam radiotherapy."

"We are excited to be among the early adopters of Scintix and to help develop this therapy for all cancer patients, especially those with stage 4 disease, where treatment options often remain very limited," he said. "With Scintix, the X1 machine and the tumor communicate continuously via a live data stream produced during patient treatment. This precision should enable us to treat less surrounding tissue and may enable the treatment of more tumors in the same course of therapy."

More on Scintix from RefleXion

The FDA clearance covers patients with lung and bone tumors. These tumors may arise from primary cancers or metastatic lesions spread from other cancers in the body.

Scintix previously had FDA breakthrough device designation for treating lung tumors, RefleXion noted. Its initial clearance allows use with the radiopharmaceutical fluorodeoxyglucose F 18—commonly known as FDG. The company plans to adapt the therapy to work with a range of radiopharmaceuticals under development for different cancer types.



Co-founder and CTO, Sam Mazin and Todd Powell, CEO and president, with the company's Scintix system.
Image courtesy of RefleXion

RefleXion's X1 machine delivers Scintix therapy — formerly called BgRT. X1 combines positron emission tomography (PET) with a linear accelerator (LINAC). This delivers a radiation dose that tracks the cancer's motion.

Immediately before treatment, a patient receives a radiopharmaceutical injection that interacts with cancer cells to produce signals or emissions. X1 continuously constructs a map from detected emissions data to determine where to aim the radiation.

"From its inception, the novel nature of Scintix therapy demanded that we fundamentally rethink how to design a machine capable of delivering cancer treatment to patients that were not considered candidates for radiotherapy because of the extent of their disease," said Todd Powell, CEO and president of RefleXion. "Likewise, our regulatory pathway encompassed unprecedented hurdles as medical device and pharmaceutical teams within the FDA worked together to create a new classification regulation for this breakthrough device and therapy.

"With initial clearance for Scintix therapy behind us, we will begin full commercialization and patient treatments in the coming weeks." **+MD**