

RefleXion Medical Company and Technology Background

RefleXion Medical is a privately held therapeutic oncology company headquartered in Hayward, California. The company was founded in 2009 by Sam Mazin, Ph.D., and Akshay Nanduri to create a new cancer treatment through biological guidance.

The two founders first met in high school in Toronto and maintained contact through college and graduate school. In 2008, Mazin contacted Nanduri with his idea about a new approach to seeing and treating cancerous tumors simultaneously. Their work led to the co-founding of RefleXion Medical and an entirely new way to use the established gold standard for cancer diagnostic imaging as a means to guide treatment delivery, thereby expanding radiotherapy as an option for patients with metastatic cancer.

Granted Breakthrough Device designation for lung tumors and marketing clearance under the De Novo pathway by the FDA, the **RefleXion® X1 machine with SCINTIX® biology-guided radiotherapy (BgRT) is designed to expand radiotherapy from single tumor to multiple tumor treatment for primary and metastatic lung or bone tumors, while also minimizing the delivery of radiation to vital, healthy tissue.** The RefleXion X1, also cleared for stereotactic body radiotherapy (SBRT), stereotactic radiosurgery (SRS), and intensity modulated radiotherapy (IMRT), improves upon the delivery of conventional radiotherapy for single-site cancers.

Cancer Guides Treatment

SCINTIX therapy is the first to use signals produced from the cancer itself to guide treatment delivery, even in tumors that are moving. The patented technology incorporates a well-established modality for cancer staging and imaging—positron-emission tomography (PET)—that enables tumors to continuously signal their location, **making treatment of metastatic cancer possible.** Using anatomic data from computed tomography (CT) and functional imaging data from PET to guide personalized radiotherapy, SCINTIX technology detects the emissions and, in about half of a second, sends beamlets of radiation directly to the tumors to destroy them.

RefleXion's SCINTIX technology is the first and only radiotherapy approach that uses a single radiotracer injection to transform cancer cells into real-time biological guides that steer radiotherapy delivery to one or multiple tumors in the same treatment session.

This new treatment offers a significant change in strategy from single tumor therapy to the ability to treat multiple targets in the same treatment session—a difficult goal for conventional radiotherapy because of the logistical patient treatment setup barriers and the amount of radiation that would be delivered to healthy cells.

Use of PET

PET makes use of a small amount of a radioactive drug, called a tracer, to highlight the differences between healthy cells and cancer cells. The most commonly used tracer is FDG, a glucose-based compound, which SCINTIX therapy uses to guide radiation to the real-time location of the tumor. Cancer cells rapidly consume the FDG, which breaks down and instantly

produces emissions, signaling their location. The real-time response to these detected emissions is the fundamental principle of SCINTIX therapy.

Combining PET and Radiotherapy

RefleXion combines PET imaging with stereotactic radiotherapy to guide radiation to the real-time location of the tumor for treatment. Current radiotherapy systems require a margin of healthy tissue around the tumor to account for positional uncertainties such as involuntary patient movements and breathing. This extra margin area often results in a significant amount of additional radiation delivered to the patient's healthy tissue. If too much healthy tissue receives radiation and the patient nears the limit of toxicity levels, less therapeutic radiation is available to ensure the effectiveness of treatment, or the ability to treat additional tumors. **By using the tumor's own emissions to guide delivery of the radiation dose, treatment margins and the subsequent radiation dose to healthy tissue may potentially be reduced.**

Traditionally, PET is used to form a complete image that takes up to an hour, during which time the tumor can change location. However, as the FDG tracer is consumed, the emissions generated are instantly available and reveal the cancer's location. The RefleXion X1 with SCINTIX technology senses the emissions and rapidly responds by sending beamlets of radiation toward the originating tumor to destroy it.

The best treatment plan for many patients combines multiple therapies. When added to chemotherapy, immunotherapy, or targeted drugs, SCINTIX therapy may improve outcomes for patients with lung and bone tumors of any stage.

The RefleXion X1 with SCINTIX therapy represents a breakthrough in cancer treatment as the only dual modality platform offering biologic guidance for tumors in motion, and anatomic guidance for earlier stage cancers with its onboard fan-beam kVCT, thereby fundamentally altering the treatment model for cancer care.

Funding, Investors and the Team

RefleXion has raised \$585M in debt and equity funding. The company is backed by premier investment firms TPG Growth/The Rise Fund, Ascension Ventures, Catalio, PSP Investments, Ally Bridge Group, KCK Group, Sofinnova Partners, Venrock, T. Rowe Price, and global pharmaceutical leaders Pfizer Ventures, and Johnson & Johnson Innovation – JJDC, Inc. The company has also received grant funding from the National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Program.

Since the company's founding in 2009, the co-founders have assembled an impressive internal team and advisory boards made up of KOLs and renowned industry veterans. Todd Powell assumed the roles of president and CEO in 2017 after a successful leadership tenure with Elekta, one of the industry's largest manufacturers of radiotherapy systems. Additionally, Sean Shirvani, M.D., who joined RefleXion in 2018, assumed the role of Chief Medical Officer in December 2020. Dr. Shirvani contributes over 15 years of clinical and industry experience, including as a faculty radiation oncologist and medical director at MD Anderson Cancer Center's Arizona affiliate.

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