News release

BioXmark® enables smaller PTV margins and may allow a significantly increased radiation dose escalation to rectal cancers

- In a clinical study, the use of BioXmark® liquid fiducials led to smaller planning target volume margins than generally used for radiotherapy boosting in rectal cancer patients
- The study was conducted by MAASTRO (NL) and the results were presented at ESTRO 2022

Copenhagen, June 14, 2022 – Nanovi informs that results of a clinical study from Maastricht University Medical Centre (MAASTRO, NL) regarding the use of BioXmark® to guide radiotherapy (RT) of rectal cancer patients were presented at the European Society of Radiation Oncology (ESTRO)’s annual congress 2022.

For the treatment of rectal cancer patients, radiation dose escalation is expected to result in an increased clinical complete response rate which may enable more patients to qualify for an organ-sparing treatment approach by the omission of surgery. The result of radiation dose escalation via RT boosts depends on good visibility of the boost target volume (GTV boost) on pre-treatment imaging to set the lowest possible RT planning target volume (PTV) margins. A promising solution to help increase the boost target visibility is the usage of fiducial markers. The aim of this study, which included nineteen (19) patients with locally advanced rectal cancer, treated with neoadjuvant chemoradiation, was to determine the required PTV margins for RT boosting when using BioXmark® liquid fiducials. BioXmark® has demonstrated good positional stability during radiation treatment and good visibility on CT and CBCT imaging without marker-related toxicity in rectal cancer patients (Opbroek, to be published).

Study results and conclusions
For the GTV boost, PTV margins to ensure a minimum dose to the clinical target volume of 95% for 90% of patients were 0.3cm, 0.8cm, and 0.3cm for the lateral, craniocaudal, and anteroposterior directions, respectively. The PTV margin to cover 90% of all fractions was 1.2cm for CTVelec.

The PTV margins were less than the margins generally used for CBCT-based radiation boost treatments for rectal cancer treatment. Based on this it was concluded that BioXmark® fiducials for CBCT marker matching may allow for significantly increased dose escalation to target volumes and reduced dose to surrounding healthy tissue compared to CBCT-based boosting without fiducials. This could represent a good alternative to MRI-linac based boosting.

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About BioXmark®

BioXmark® is a liquid fiducial marker, developed by Nanovi to radiographically mark soft tissue for target visibility on imaging and enable high precision radiation therapy for multiple cancer types.

BioXmark® is CE marked and commercially available in Europe. In March 2022, BioXmark® was submitted to the FDA for market approval in the U.S.

BioXmark® has the following features and benefits:

- *Liquid nature* for customizable implantation
- *Sticky and tissue-adaptive* with positional stability and visibility on relevant imaging modalities, including MRI
- *Non-metallic composition* for a low level of artefacts and low dose perturbation offering compatibility with photon and proton radiation therapies

About Nanovi

Nanovi A/S is a Danish medical implant company specializing in precision marking for better cancer therapy. Our corporate dedication is to empower healthcare professionals with the best possible tools to support the delivery of high precision radiation therapy and surgery for the benefit of cancer patients and for healthcare efficiency.

We have a portfolio of unique in-house developed liquid fiducial markers for both human and veterinary use.

All our products are derived from a patented carbohydrate technology platform, co-invented with and licensed from the Department of Health Technology at the Technical University of Denmark, DTU.

For more information, please visit: [www.nanovi.com](http://www.nanovi.com)