

News release

## BioXmark® demonstrates strong performance to enable radiotherapy boosting in rectal cancer patients

- The publication of a clinical study by MAASTRO, NL, provides evidence for the liquid marker's feasibility to guide IGRT of patients with rectal cancer

Copenhagen, December 5, 2022 – Nanovi informs that the results of a clinical performance study of its liquid fiducial marker, BioXmark®, by Maastricht University Medical Centre (MAASTRO, NL) have been published in the journal *Clinical and Translational Radiation Oncology*. The study evaluated the feasibility of BioXmark® to guide radiotherapy boosting in patients with rectal cancer.

### The study reveals the following main conclusions:

- BioXmark® remained positionally stable in 96% of rectal cancer cases
- BioXmark® showed good visibility on planning CT without artifacts impacting image interpretation
- 98.5 % of the BioXmark® markers were visible on daily CBCT
- The study provided evidence of the feasibility of BioXmark® to guide image-guided radiotherapy

**Background and study design:** Dose-escalation in radiation therapy of rectal cancer may result in an increased complete response rate and thereby help to avoid surgery and ensure organ preservation. To allow increased dose escalation, it is crucial to have a technique that allows for accurate image-guided radiotherapy.

The aim of the current study was to evaluate the performance of BioXmark® during a course of radiotherapy in patients with rectal cancer. BioXmark® was evaluated on its positional stability, technical feasibility, visibility on different imaging modalities and safety in this prospective, non-randomized, single-arm feasibility trial. The trial included twenty patients with locally advanced rectal cancer referred for neoadjuvant chemoradiotherapy.

**Results:** Seventy-four BioXmark® markers from twenty patients were available for analysis. The marker was stable in 96% of the cases. Only one marker showed clinically relevant migration, one marker was lost before the first treatment and one marker was lost during treatment. Marker visibility was good on computed tomography (CT) and cone-beam CT (CBCT) without artifacts impacting image interpretation. No adverse events were reported shortly after injection or during radiotherapy in any of the patients. Moreover, pathology did not report any substantial local tissue inflammation.



**Conclusion:** The study provided evidence of the feasibility of BioXmark® for image-guided radiotherapy on daily CBCT to allow for increased dose escalation for patients with rectal cancer. The marker may provide a tool for accurate determination of the day-to-day tumor location and thereby allow for safe dose-escalation.



**Nanovi contact:**

Jesper Boysen, CEO  
Phone: +45 24 65 60 33  
E-mail: [jb@nanovi.com](mailto:jb@nanovi.com)

**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 artifacts and low dose perturbation offering compatibility with photon and proton radiation therapies

**About Nanovi**

Nanovi (Nanovi A/S) is a Danish medical device company specializing in implantable liquid tissue markers for better cancer therapy. The 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.

Nanovi is the developer and manufacturer of BioXmark® and PetXmark™, two liquid tissue markers to radiographically mark soft tissue for high-precision radiation therapy of human and veterinary patients, respectively.

Nanovi's liquid tissue markers 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)