

News release

BioXmark® is made available for all participants in the PROTECT esophagus cancer trial

- **PROTECT is a multicenter European clinical study comparing proton and photon radiation therapy as a part of neoadjuvant chemoradiation for patients with resectable esophageal cancer**
- **The use of fiducial markers is an option in the study protocol, and BioXmark® is a liquid fiducial marker that has demonstrated good performance, safety and technical feasibility in esophageal cancer treatment**

Copenhagen, April 1, 2022 – The PROTECT trial is an open-label, non-blinded, international multicenter, randomized clinical phase III study for patients with operable esophageal cancer or esophagogastric cancer. In the study, patients will be randomized to receive either neoadjuvant chemoradiotherapy (standard of care) or neoadjuvant chemo-proton-therapy (intervention). The overall objective of the trial is to test the hypothesis that proton therapy enabled radiation dose reductions to sensitive, normal tissues will result in lower rates of treatment-related pulmonary complications in esophageal cancer compared to standard photon therapy.

The study is projected to run over 6 years, from 2021 to 2027, involving more than 30 clinical sites in 9 countries and enrolling close to 400 patients. The primary study endpoint is the incidence of pulmonary complications during and following neoadjuvant chemoradiotherapy or neoadjuvant chemo-proton-therapy - and surgery. The proportion of patients with pulmonary complications will be compared between the two arms.

BioXmark® is a liquid fiducial marker that has demonstrated good performance, safety and technical feasibility across a number of organs including the esophagus (1,2). The liquid marker stands out also, having shown low dose perturbation for compatibility with both photon and proton therapy. BioXmark® is developed and marketed in Europe by Nanovi to radiographically mark soft tissue for enhanced target visibility on imaging.

Nanovi has agreed to make BioXmark® available, free of charge, for all participants in the multicenter PROTECT esophagus cancer trial. The use of fiducial markers is an option under the trial protocol to support the accurate delivery of radiation therapy.

For participants in the PROTECT trial:

A one-page introduction to BioXmark® and to the use of the liquid marker in esophageal cancer has been included with the study protocol. For further information on the product, including scientific publications, white papers, introduction video and user guidance, please contact Nanovi.



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About BioXmark®- the liquid fiducial marker

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

BioXmark® has the following features and benefits:

- *Liquid nature* for customizable implantation
- *Sticky and soft markers* with positional stability and visibility on relevant imaging modalities, including MRI
- *Non-metallic* for a low level of artefacts and low dose perturbation ensuring photon and proton compatibility

BioXmark® offers radiation therapy workflow benefits in the form of

- A fast and easy implantation procedure
- Less risk for procedure-related complications
- No need for additional training or special equipment

About Nanovi

Nanovi A/S is a Danish medical implant company specialized 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

References:

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2. de Blanck SR, Scherman-Rydhög J, Siemsen M, Christensen M, Baeksgaard L, Irming Jølk R, et al. Feasibility of a novel liquid fiducial marker for use in image guided radiotherapy of oesophageal cancer. *Br J Radiol*. 2018 Dec;91(1092):20180236.