News release

Nanovi has submitted BioXmark®, its liquid fiducial marker, for FDA approval

- **The U.S. represents the world's largest market for precision marking in cancer therapy**

Copenhagen, April 4, 2022 – Nanovi informs that in March 2022, the company completed the submission of a De Novo classification request for BioXmark® to the U.S. Food and Drug Administration (FDA) in order to achieve market authorization for the product in the U.S.. The submission follows communication between Nanovi and FDA, including a pre-submission meeting held in 2021.

BioXmark® is a novel liquid soft tissue marker, developed by Nanovi to enhance target visibility in imaging and guide high precision radiation therapy for multiple cancer types. Nanovi obtained CE marking of BioXmark® in 2020, and the product has since then been commercially available across all EU member states.

The U.S. has 2.56 million new cancer cases annually and is the world's biggest cancer therapy market. For most solid cancers, radiation therapy in combination with surgery and/or chemotherapy is a first-line treatment option. In radiation therapy, precision is essential to effectively kill cancer cells and minimize radiation damage to surrounding healthy tissue and organs for optimal patient outcomes.

In a comment to the U.S. regulatory submission of BioXmark®, Jesper Boysen, CEO of Nanovi, said: "*The submission of our U.S. regulatory file on BioXmark® is a significant milestone. As a liquid fiducial marker, BioXmark® has demonstrated clinical performance to potentially open new opportunities in high precision radiation therapy. Our product builds on a unique technology platform developed in collaboration with the Technical University of Denmark. We now look forward to our continued interactions with the FDA.*"

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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 target visibility on imaging and to 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