

NANOBIOTIX

EXPANDING LIFE

Nanobiotix Announces Publication of New Clinical Case Study Highlighting First Patient Experience of NBTXR3 Treatment for Pancreatic Cancer

February 9, 2022

[Data published in *Clinical and Translational Radiation Oncology*](#)

- Peer-reviewed clinical case study reported preliminary data on the first-in-human administration of NBTXR3 for the treatment of pancreatic cancer not eligible for surgery, demonstrating feasibility with no treatment-related toxicity
- Case study provides the first demonstration of local endoscopic delivery of NBTXR3 to a deep visceral tumor, and adds to a growing body of clinical data suggesting injection feasibility in pancreatic cancer, head and neck cancer, lung cancer, liver cancer, colorectal cancer, esophageal cancer, prostate cancer and soft tissue sarcoma

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 9, 2022-- Regulatory News:

[NANOBIOTIX](#) (Euronext: NANO – NASDAQ: NBTX – the “**Company**”), a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced the publication of a peer-reviewed case study by researchers at The University of Texas MD Anderson Cancer Center in *Clinical and Translational Radiation Oncology*. The case study reports on the first patient experience of treatment with potential first-in-class radioenhancer, NBTXR3, in pancreatic ductal adenocarcinoma (PDAC; pancreatic cancer).

Given the nature of NBTXR3 as a therapeutic candidate with potentially broad applicability across solid tumor indications and therapeutic combinations, Nanobiotix and MD Anderson are collaborating to expand development of NBTXR3 beyond the Company’s priority pathways in locally advanced head and neck squamous cell carcinoma and immunotherapy. This ongoing phase I pancreatic cancer study is one of five active phase I or phase II studies currently being conducted as part of the collaboration.

The phase I clinical trial is designed to determine the safety profile of NBTXR3 activated by radiotherapy (RT) for patients with locally advanced or borderline resectable PDAC, and the recommended phase II dose (RP2D) for future efficacy evaluation. The case study in *Clinical and Translational Radiation Oncology* reports on the first patient ever to receive local endoscopic delivery of NBTXR3 to a deep visceral tumor. The patient is a 66-year-old male with unresectable, locally advanced PDAC who received local endoscopic delivery of NBTXR3 followed by intensity modulated RT. CT imaging demonstrated no visible leakage of the radioenhancer outside of the injected tumor. At initial follow-up evaluation, the lesion remained radiographically-stable, the patient did not demonstrate treatment-related toxicity, and the report concluded that the treatment was feasible.

PDAC is one of the leading causes of cancer-related death in the world today. For patients with PDAC who are not eligible for surgery, RT has been shown to improve local disease control. However, safely delivering therapeutic doses of radiation remains challenging due to off-target toxicities in surrounding healthy tissues. While systemic radiosensitizers have been evaluated in this indication, these agents increase the sensitivity of both tumor tissues and healthy tissues. In contrast, due to the potential of NBTXR3 to increase the dose of RT within the tumor without increasing the dose in surrounding healthy tissues, the radioenhancer is being evaluated as a new option to address this urgent unmet need.

“There is a critical need to develop an effective therapy to improve treatment outcomes while mitigating off-target toxicities for patients with locally advanced pancreatic cancer,” said Eugene Koay, MD, PhD, associate professor of Radiation Oncology at MD Anderson. “The initial feasibility for NBTXR3 injection outlined in this case study provides an important step forward as we determine the recommended phase II dose and the potential for the radioenhancer to help patients with this challenging disease.”

Nanobiotix expects to establish the recommended phase II dose for NBTXR3 in pancreatic cancer in 2022.

About NBTXR3

NBTXR3 is a novel, potentially first-in-class oncology product, composed of functionalized hafnium oxide nanoparticles that is administered via one-time intratumoral injection and activated by radiotherapy. The product candidate’s physics-based mechanism of action (MoA) is designed to induce significant tumor cell death in the injected tumor when activated by radiotherapy, subsequently triggering adaptive immune response and long-term anti-cancer memory. Given the MoA, Nanobiotix believes that NBTXR3 could be scalable across any solid tumor that can be treated with radiotherapy and across any therapeutic combination, particularly, with immune checkpoint inhibitors.

NBTXR3 is being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) as the primary development pathway. The company-sponsored phase I dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy. In February 2020, the United States Food and Drug Administration granted regulatory Fast Track designation for the investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced HNSCC who are not eligible for platinum-based chemotherapy.

Nanobiotix has also prioritized an Immuno-Oncology development program—beginning with a Company sponsored phase I clinical study, evaluating NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors for patients with locoregional recurrent or recurrent/metastatic

HNSCC and for patients with lung or liver metastases from any primary cancer eligible for anti-PD-1 therapy, either naïve or resistant to prior PD-1 (either primary or secondary as per SITC criteria).

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in strategic collaborations to expand development of the product candidate in parallel with its priority development pathways. Pursuant to this strategy, in 2019 Nanobiotix entered into a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center to sponsor several phase I and phase II studies to evaluate NBTXR3 across tumor types and therapeutic combinations. In 2021, the Company entered into an additional strategic collaboration agreement with LianBio to support its global phase III study in Asia along with four future registrational studies.

About NANOBOTIX

Nanobiotix is a late-stage clinical biotechnology company pioneering disruptive, physics-based therapeutic approaches to revolutionize treatment outcomes for millions of patients; supported by people committed to making a difference for humanity. The company's philosophy is rooted in the concept of pushing past the boundaries of what is known to expand possibilities for human life.

Incorporated in 2003, Nanobiotix is headquartered in Paris, France. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, Germany and Switzerland.

Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 umbrella patents associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system. The company's resources are primarily devoted to the development of its lead product candidate— NBTXR3 —which is the product of its proprietary oncology platform and has already achieved market authorization in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on [LinkedIn](#) and [Twitter](#).

Disclaimer

This press release contains certain "forward-looking" statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as "at this time," "anticipate," "believe," "expect," "intend," "on track," "plan," "scheduled," and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, include statements about the timing and progress of clinical trials, the timing of our presentation of data, the results of our preclinical and clinical studies and their potential implications. Such forward-looking statements are made in light of information currently available to us and based on assumptions that Nanobiotix considers to be reasonable. However, these forward-looking statements are subject to numerous risks and uncertainties, including with respect to the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data notwithstanding positive early clinical results and the risks associated with the evolving nature of the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to it. Furthermore, many other important factors, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 7, 2021 under "Item 3.D. Risk Factors" and those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers – the AMF) on April 7, 2021, each as updated in our Half-Year Financial Report filed with the AMF and the SEC on September 8, 2021 (a copy of which is available on www.nanobiotix.com), as well as other known and unknown risks and uncertainties may adversely affect such forward-looking statements and cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220209005896/en/): <https://www.businesswire.com/news/home/20220209005896/en/>

Nanobiotix

Communications Department

Brandon Owens

VP, Communications

+1 (617) 852-4835

contact@nanobiotix.com

Investor Relations Department

Kate McNeil

SVP, Investor Relations

+1 (609) 678-7388

investors@nanobiotix.com

Media Relations

FR – Ulysse Communication

Pierre-Louis Germain

+ 33 (0) 6 64 79 97 51

plgermain@ulysses-communication.com

US – Porter Novelli

Dan Childs

+1 (781) 888-5106

Dan.childs@porternovelli.com

