

PRESS RELEASE

NANOBIOTIX ANNOUNCES FIRST PATIENT INJECTED WITH NBTXR3 IN PANCREATIC CANCER AND SAFE TO PROCEED NOTIFICATIONS FOR TWO ADDITIONAL TRIALS FROM U.S. FDA

- **First patient injected in phase I trial evaluating NBTXR3 activated by radiation therapy for patients with pancreatic cancer at The University of Texas MD Anderson Cancer Center in clinical collaboration with Nanobiotix**
- **'Safe to proceed' notifications have been received from the United States Food and Drug Administration for two additional trials—a phase I trial evaluating NBTXR3 activated by radiation therapy for patients with lung cancer and a phase I trial evaluating NBTXR3 activated by radiation therapy for patients with esophageal cancer**
- **These trials are executed within the scope of an existing clinical collaboration agreement and do not represent incremental costs for the company beyond previously announced financial terms**

“Development of NBTXR3 activated by radiation therapy across several solid tumor indications is critical to our mission of expanding the potential use of our product to as many patients as possible. Our clinical collaboration agreement with The University of Texas MD Anderson Cancer Center provides additional capabilities and expertise to help develop this novel product for patients with high unmet needs. The first injection in pancreatic cancer represents a major milestone for the development of NBTXR3, as it brings the product to its seventh indication in a clinical trial setting. This milestone, along with upcoming trials in lung cancer and esophageal cancer, show the ongoing progress of our collaboration agreement and our development pipeline overall.” – Laurent Levy, CEO of Nanobiotix

Paris, France ; Cambridge, Massachusetts (USA) ; October 13, 2020 - [NANOBIOTIX](#) (Euronext: NANO - ISIN: FR0011341205 – the **“Company”**), a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced that the first patient has been injected in its phase I study evaluating NBTXR3 activated by radiation therapy for patients with pancreatic cancer. The trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson) as part of an ongoing clinical collaboration.

Two additional trials from the clinical collaboration received 'safe to proceed' notifications from the United States Food and Drug Administration (FDA): (i) a phase I study evaluating NBTXR3 activated by radiation therapy for patients with lung cancer amenable to re-irradiation; and (ii) a phase I study evaluating NBTXR3 activated by radiation therapy with concurrent chemotherapy for patients with esophageal cancer. All current and future trials in this clinical collaboration are sponsored and executed by MD Anderson.

A Phase I Study Evaluating NBTXR3 Activated by Radiation Therapy in Patients with Pancreatic Cancer

Pancreatic cancer is a rare, deadly disease that accounts for approximately 3% of all cancers and has a 5-year survival rate of 9%¹.

This pancreatic cancer trial is an open-label, single-arm, prospective phase I study consisting of two parts: (i) dose-escalation to determine the recommended phase 2 dose (RP2D) of NBTXR3 activated by radiation therapy; and (ii) expansion at RP2D.

The patient population will include adults (age ≥ 18 years) with borderline resectable pancreatic cancer (BRPC) or locally advanced pancreatic cancer (LAPC) that are radiographically non-metastatic at screening, and that have not previously received radiation therapy or surgery for pancreatic cancer. Up to 24 subjects will be enrolled and the planned enrollment period is 18 months.

The objectives of the study are the determination of dose-limiting toxicity (DLT), the maximum tolerated dose (MTD), and the RP2D.

¹ <https://www.cancer.net/cancer-types/pancreatic-cancer/statistics>

Two Additional Phase I Studies in Lung and Esophageal Cancer Pending

A phase I trial investigating NBTXR3 activated by radiation therapy for patients with lung cancer amenable to re-irradiation, and a phase I trial investigating NBTXR3 activated by radiation therapy with concurrent chemotherapy for patients with esophageal cancer have been deemed 'safe to proceed' by FDA. 'Safe to proceed' notifications are delivered once the agency is satisfied with the information contained in an investigational new drug application (IND) or any additional information or clarification has been provided.

Lung cancer is the second most common cancer type, and the leading cause of cancer death for both men and women. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, with a 5-year survival rate of 24% worldwide.²

The lung cancer trial is an open-label, two-cohort, prospective phase I study consisting of two parts: (i) a radiation therapy safety lead-in, and NBTXR3 activated by radiation therapy dose-finding to determine the RP2D; and (ii) expansion at the RP2D with toxicity monitoring.

The patient population will include adults (age ≥ 18 years) with inoperable, locoregional recurrent (LRR) non-small cell lung cancer (NSCLC) stage IA to IIIC that are radiographically non-metastatic at screening and have previously received definitive radiation therapy. Cohort 1 will evaluate the safety of intensity-modulated radiation therapy (IMRT) monotherapy in 10 patients. Up to 24 subjects will be enrolled in cohort 2. Recruitment is expected to begin in 4Q2020 and the planned enrollment period is 36 months.

Esophageal cancer is the eighth most common cancer type and the sixth most common cause of cancer deaths worldwide. The 5-year survival rate in the US is 20%, and 10% in Europe³.

The esophageal cancer trial is an open-label, single-arm, prospective phase I study consisting of two parts: (i) dose-escalation to determine the RP2D of NBTXR3 activated by radiation therapy with concurrent chemotherapy, as per standard of care; and (ii) expansion at the RP2D with toxicity monitoring.

The patient population will include adults (age ≥ 18 years) with stage II-III adenocarcinoma of the esophagus that are treatment naïve and radiographically non-metastatic at screening. Up to 24 subjects will be enrolled. Recruitment is expected to begin in 4Q2020 and the planned enrollment period is 24 months.

Next Steps for Clinical Collaboration with MD Anderson

The clinical collaboration between Nanobiotix and MD Anderson includes plans for additional clinical trials across several indications. Beyond the three (3) trials mentioned above, the other trials, including four (4) combination trials with immune checkpoint inhibitors and NBTXR3 activated by radiation therapy, are in preparation and will launch in due time.

About NBTXR3

NBTXR3 is a novel radioenhancer composed of functionalized hafnium oxide nanoparticles that is administered via one-time intra-tumoral injection and activated by radiation therapy. The physical and universal mode of action (MoA) of NBTXR3 is designed to trigger cellular destruction death and adaptive immune response.

NBTXR3 is being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) of the oral cavity or oropharynx in elderly patients unable to receive chemotherapy or cetuximab with limited therapeutic options. Promising results have been observed in the phase I trial regarding local control. In the United States, the Company has started the regulatory process to commence a phase III clinical trial in locally advanced head and neck cancers. In February 2020, the United States Food and Drug Administration granted the 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 head and neck squamous cell cancer who are not eligible for platinum-based chemotherapy.

Nanobiotix is also running an Immuno-Oncology development program. The Company has launched a Phase I clinical trial

² <https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics>

³ <https://www.cancer.net/cancer-types/esophageal-cancer/statistics>

of NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors in locoregional recurrent (LRR) or recurrent and metastatic (R/M) HNSCC amenable to re-irradiation of the HN and lung or liver metastases (mets) from any primary cancer eligible for anti-PD-1 therapy.

Other ongoing NBTXR3 trials are treating patients with hepatocellular carcinoma (HCC) or liver metastases, locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and pancreatic cancer. The Company is also engaged in a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center to further expand the NBTXR3 development program.

About NANOBIOTIX: www.nanobiotix.com

Incorporated in 2003, Nanobiotix is a leading, clinical-stage nanomedicine company pioneering new approaches to significantly change patient outcomes by bringing nanophysics to the heart of the cell.

The Nanobiotix philosophy is rooted in designing pioneering, physical-based approaches to bring highly effective and generalized solutions to address unmet medical needs and challenges.

Nanobiotix's novel, proprietary lead technology, NBTXR3, aims to expand radiotherapy benefits for millions of cancer patients. Nanobiotix's Immuno-Oncology program has the potential to bring a new dimension to cancer immunotherapies.

Nanobiotix is listed on the regulated market of Euronext in Paris (Euronext: NANO / ISIN: FR0011341205; Bloomberg: NANO: FP). The Company's headquarters are in Paris, France, with a US affiliate in Cambridge, MA, and European affiliates in France, Spain and Germany.

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