

PRESS RELEASE

NANOBIOTIX ANNOUNCES FIRST PHASE I TRIAL WITH NBTXR3 IN PANCREATIC CANCER IS SAFE TO PROCEED PER US FDA

- **The trial is a phase I dose escalation study evaluating the safety and feasibility of NBTXR3 activated by radiation therapy in patients with locally advanced or borderline-resectable pancreatic ductal adenocarcinoma**
- **The trial will recruit up to approximately 24 patients with a planned enrollment period of 18 months**

“The launch of the first trial from our clinical collaboration with MD Anderson is another step forward for NBTXR3 activated by radiation therapy, and we are excited to expand into pancreatic cancer which is a new indication for us. We are pleased that the FDA has been able to advance the regulatory process in this complex environment. We look forward to the opportunity to begin treating pancreatic cancer patients and finding ways to make a difference in their lives.” – Laurent Levy, CEO of Nanobiotix

Paris, France ; Cambridge, Massachusetts (USA) ; May 6, 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 protocol for the first trial from its clinical collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson) has been designated as “safe to proceed” by the US Food and Drug Administration (FDA). The trial was co-developed with Nanobiotix and MD Anderson is the sponsor and executor of the trial.

The investigational new drug application (IND), covers a phase I study evaluating the safety and feasibility of NBTXR3 activated by radiation therapy for patients with locally advanced (LAPC) or borderline resectable (BRPC) cases of pancreatic ductal adenocarcinoma (PDAC). This trial is the first to evaluate NBTXR3 activated by radiation therapy in pancreatic cancer.

Significant Unmet Needs and Opportunity in Pancreatic Cancer

Pancreatic cancer is a rare, deadly disease. Given that surgery with R0 resection (i.e. macroscopically complete tumor removal with negative microscopic surgical margins) remains the only hope for long-term survival, clinical trials have investigated various neoadjuvant strategies—wherein patients receive anti-cancer drugs or radiation prior to surgery—to increase the surgery-eligible population while also increasing the R0 resection rate.

In support of the rationale for neoadjuvant therapy, a retrospective analysis demonstrated a near doubling in overall survival (OS) in PDAC patients who underwent surgery, which was attributed, at least in part, to the increased proportion of BRPC patients who became eligible for surgery as a result of neoadjuvant intervention. Importantly, there are also select cases of LAPC patients being considered for surgical resection based on their response to therapy. Given the poor prognosis of PDAC, therapeutic regimens able to increase the proportion of BRPC and LAPC patients eligible for surgery could improve survival outcomes in this population with unmet need.

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

The MD Anderson 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); and (ii) expansion at RP2D.

The patient population will include adults (age ≥ 18 years) with BRPC or LAPC that are radiographically non-metastatic at screening, and that have not previously received radiation therapy or surgery for pancreatic cancer. The number of participants enrolled will be determined based on the maximum number required to establish the RP2D. Up to 24 subjects will be enrolled, including a maximum of 12 subjects with LAPC for the dose-finding part. Twelve additional subjects with either LAPC or BRPC will be enrolled for the RP2D expansion. The planned enrollment period is 18 months. The first patient should be injected the summer of 2020.

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

(MTD), and the RP2D.

About NBTXR3

NBTXR3 is a first-in-class product designed to destroy tumors through physical cell death when activated by radiotherapy. NBTXR3 has a high degree of biocompatibility, requires one single administration before the first radiotherapy treatment session, and has the ability to fit into current worldwide radiation therapy standards of care. The physical mode of action of NBTXR3 makes it applicable across solid tumors such as lung, prostate, liver, glioblastoma, pancreas, and breast cancers.

NBTXR3 is actively being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) of the oral cavity or oropharynx in elderly and frail 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 IND process to commence a phase III clinical trial in locally advanced head and neck cancers.

Nanobiotix is also running an Immuno-Oncology development program. Pursuant to an effective IND, the Company has launched a clinical trial of NBTXR3 activated by radiotherapy in combination with anti-PD-1 antibodies 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.

The 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 prostate adenocarcinoma. The company has a large-scale, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (9 new phase I/II clinical trials in the United States) to evaluate NBTXR3 across head and neck, pancreatic, lung, gastrointestinal and advanced cancers..

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 first-in-class, 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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the reference document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-018 on April 30, 2019 (a copy of which is available on www.nanobiotix.com) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.