PRESS RELEASE

NANOBIOTIX ANNOUNCES TWO NEW PHASE II TRIALS EVALUATING NBTXR3 IN COMBINATION WITH ANTI-PD-1 FOR THE TREATMENT OF HEAD AND NECK CANCER

- **Two new studies have received 'Safe to Proceed' notifications from the United States Food and Drug Administrations and are pending activation:**
  - **A phase II study of NBTXR3 activated by radiation and combined with pembrolizumab for patients with recurrent or metastatic head and neck squamous cell carcinoma with limited PD-L1 expression or refractory to PD-1 blockade**
  - **A phase II study of reirradiation with NBTXR3 in patients with inoperable locoregional recurrent head and neck squamous cell carcinoma**
- **Following the release of positive first results from the Company's phase I immunotherapy trial, these trials highlight the continued expansion of the development plan for NBTXR3 in combination with checkpoint inhibitors and could present additional opportunities to accelerate the pipeline**

"Overcoming low response rates in cancer immunotherapy is a major opportunity for advancement in our field. Combined with the fact that many patients have no other options if immunotherapy does not work, addressing this unmet medical need is critical to our mission of treating as many patients as possible with NBTXR3. With recent positive results from our phase I I/O trial, the pending activation of two phases II trials evaluating NBTXR3 with checkpoint inhibitors highlights the momentum of NBTXR3 development." – Laurent Levy, CEO of Nanobiotix

Paris, France ; Cambridge, Massachusetts (USA) ; November 17, 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 United States Food and Drug Administration (FDA) has provided 'Safe to Proceed' notifications for two additional trials in its ongoing clinical collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson). These trials were co-developed with Nanobiotix and MD Anderson is the sponsor and executor.

Significant Unmet Needs and Opportunity in Cancer Immunotherapy

Cancer immunotherapies such as immune checkpoint inhibitors (ICIs) have shown promising clinical outcomes over the past two decades; and are often used for patients with advanced cancers once other therapies have reached the end of their effectiveness. However, the vast majority of patients only receive a temporary benefit or no benefit from ICIs, as they either develop resistance to the treatment during the course of therapy or are non-responsive to the treatment altogether (only 15%-20% of patients respond, according to published data). These barriers present a significant unmet need to improve the efficacy ICIs and expand their potentially curative benefits to more patients with advanced cancers.

Combining ICIs with radiation therapy is emerging as a valuable strategy to "prime" an immune response and thereby increase the response rate, however the efficacy of radiation therapy is limited by toxicities related to the exposure of healthy tissues.

NBTXR3 is injected one time, directly into solid tumors. The product candidate is designed to increase the energy deposit from radiation therapy within the target tumor and subsequently increase the tumor-killing effect without increasing toxicity in surrounding healthy tissue. Pre-clinical and clinical data also suggest that NBTXR3 activated by radiation therapy can prime the immune system, creating an anti-tumor immune response that produces both local and systemic effects.

A Phase II Study of NBTXR3 Activated by Radiation and Combined with Pembrolizumab for Patients with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma with Limited PD-L1 Expression or Refractory to PD-1 Blockade

This MD Anderson trial is an open label, two cohort, non-randomized phase II study. The primary objective of the study is to evaluate tumor response of NBTXR3 activated by radiation therapy in combination with

pembrolizumab in patients with recurrent or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).

The population includes patients with inoperable R/M HNSCC of the oropharynx, oral cavity, hypopharynx, larynx or neck. Patients could be anti-PD-1/L1 naïve or refractory. Up to 60 patients may be treated, with up to 40 in the first cohort and up to 20 in the second cohort. The first cohort will include anti-PD-1/L1 naïve patients with a combined positive score (CPS) between greater than or equal to 1% and less than 20%. The second cohort will include anti-PD-1/L1 refractory patients irrespective of PD-L1 expression.

A Phase II Study of Reirradiation with NBTXR3 in Patients with Inoperable Locoregional Recurrent Head and Neck Squamous Cell Carcinoma

This MD Anderson trial is an open label, two cohort, non-randomized phase II study. The primary objectives of the study are: (i) to estimate progression-free survival (PFS) and the early clinical benefit in patients treated with NBTXR3 activated by SBRT re-irradiation, with concurrent pembrolizumab; (ii) to assess the safety profile and estimate the early clinical benefit of NBTXR3 activated by a reduced dose of IMRT or IMPT re-irradiation with concurrent pembrolizumab.

The population includes patients with inoperable, locoregional recurrent head and neck squamous cell carcinoma (HNSCC) or second primary HNSCC, previously treated with definitive radiation therapy and without radiographic evidence of metastases. Patients could be anti-PD-1/L1 naïve or non-responders. Up to 80 patients may be treated, with up to 60 in the SBRT cohort and up to 20 in the IMRT/IMPT cohort.

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About NBTXR3

NBTXR3 is a novel, potentially first-in-class radioenhancer composed of functionalized hafnium oxide nanoparticles that is administered via one-time intra-tumoral injection and activated by radiation therapy. The primary mode of action (MoA) of NBTXR3 is designed to generate increased cellular destruction when activated by radiation therapy without increasing damage to healthy tissues. Subsequently, this cellular destruction also triggers an 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 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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