Nanobiotix: Update on Head and Neck Phase I/II Trial with NBTXR3 and Other program data presented at ImmunoRad 2018

- **Strengthening of NBTXR3 data showing the potential impact on survival in elderly and frail patients with locally advanced head and neck cancers**
- **Biomarker analysis from soft tissue sarcoma clinical trial and new preclinical data supporting NBTXR3 mechanism of action in immune-oncology and its use in combination with immune checkpoint inhibitors**

Paris, France and Cambridge, Massachusetts, USA, September 20, 2018 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announces it will present an update on and data from its NBTXR3 development program at the International Conference on Immunotherapy Radiotherapy Combinations that will take place from September 20 to 22, 2018 in Paris, France.

Follow-up of Phase I/II in advanced Head and Neck cancers in elderly and frail patients ineligible for cisplatin or intolerant to cetuximab

In the Phase I part of this trial, which is conducted to determinate the recommended dose, 18 patients have been injected with NBTXR3. Follow-up of patients that received highest doses of NBTXR3 (15% and 22% dose levels) shows that every patient alive at the 12-month cut-off date was still alive after 23 months or more. At 26 months, one of the patients treated at the 15% dose level had died.

These data suggest the potential of NBTXR3 to impact survival for this advanced cancer patient population.

Immuno biomarker study in randomized phase II/III soft tissue sarcoma clinical trial

Immunohistochemistry analyses revealed that, compared to radiation therapy alone (29 patients), NBTXR3 activated by radiation therapy (23 patients) increased the density of CD8+ T cell lymphocyte, and decreased FOXP3+ (Treg) into the tumors, while macrophage number remained relatively constant. These data indicate that NBTXR3 activated by radiation therapy could modulate the antitumor immune response.

***In vivo* investigation of NBTXR3 mode of action inducing distant immune response on CT26 tumoral model**

Depletion experiment of CD8+ T cells (NBTXR3+3x4Gy+anti-CD8) induces a partial loss of tumor growth control of treated tumors, and a complete abolition of the abscopal effect (distal tumors). This result indicates that the abscopal effect was driven by CD8+ T cells. Interestingly, depletion of CD4+ T cells (NBTXR3+3x4Gy+anti-CD4) increases the efficacy of NBTXR3 + radiation therapy at both sites (treated and distal tumors). As anti-CD4 treatment lead to Treg depletion (known to have a protumoral role), Treg depletion might have improved NBTXR3 radiation therapy treatment. These observations continue to support the rationale for the use of NBTXR3 activated by radiation therapy to seek to transform tumors into an *in situ* cancer vaccine and its potential use in combination with immunotherapeutic agents.

International Conference on Immunotherapy Radiotherapy Combinations

September 20 to 22, 2018 - Paris, France

http://www.radio-immuno.siricsocrate.fr/en/.

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About NBTXR3

NBTXR3 is a first-in-class product designed to destroy, when activated by radiotherapy:

- tumors through physical cell death
- metastasis due to immunogenic cell death leading to activation of the immune system

NBTXR3 has a high degree of biocompatibility, requires one single administration before the whole radiotherapy treatment and Nanobiotix believes has the ability to fit into current worldwide standards of radiation care.

Nanobiotix's broad clinical program includes 10 patient population evaluated in 7 clinical trials.

In June 2018, Nanobiotix established human proof of concept for this first-in-class product in its Soft tissue Sarcoma Phase III clinical trial.

NBTXR3 is actively being evaluated in head and neck cancer with locally advanced squamous cell carcinoma of the oral cavity or oropharynx in elderly and frail patients that are unable to receive chemotherapy or cetuximab with very limited therapeutic options. The Phase I/II trial has already delivered very promising results regarding the local control of the tumors.

Nanobiotix is running an Immuno-Oncology development program . In the United States., Nanobiotix has received the FDA's approval to launch a clinical study of NBTXR3 activated by radiotherapy in combination with anti-PD1 antibodies in lung, and head and neck cancer patients (head and neck squamous cell carcinoma and non-small cell lung cancer).

The other ongoing NBTXR3 studies are treating patients with liver cancers (hepatocellular carcinoma and liver metastasis), locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma.

The first market authorization process (CE Marking) is ongoing in Europe in the soft tissue sarcoma indication.

About NANOBIOTIX: www.nanobiotix.com

Incorporated in 2003, Nanobiotix is a leading, late 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 one rooted in designing pioneer physical based approaches to bring highly effective and generalized solutions to address high unmet medical needs and challenges.

Nanobiotix's first-in-class, proprietary lead technology, NanoXray, aims to expand radiotherapy benefits for millions of cancer patients. Furthermore, 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 based in Paris, France, with a U.S. affiliate in Cambridge, MA, and european affiliates in Spain and Germany.

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