*PRESS RELEASE*

# NANOBIOTIX ANNOUNCES POSITIVE FIRST RESULTS FROM PHASE I EXPANSION IN LOCALLY ADVANCED HEAD AND NECK CANCER AT ASCO 2020

- **First results from the expansion part of the Company's phase I trial, evaluating the potential of first-in-class NBTXR3 to improve treatment outcomes for elderly patients with locally advanced head and neck cancer ineligible for chemotherapy or intolerant to cetuximab, were presented today at ASCO 2020**
- **NBTXR3 has been administered to 40 patients in the trial and was well tolerated, maintaining the safety profile observed in the dose escalation part of the phase I study**
- **Analysis of 30 evaluable patients for efficacy showed a primary tumor objective response rate of 83%, including a complete response rate of 60% in the target lesion, which are the co-primary endpoints of the study**
- **The high rate of ORR observed in the escalation phase (69%) has been further improved in the expansion phase part, to reach 83%**
- **Preliminary safety and efficacy data further reinforce NBTXR3 as a potential new option for head and neck cancer patients**

*"Elderly head and neck cancer patients are currently underserved by the standard of care. Those ineligible to receive chemotherapy or intolerant to cetuximab are treated with radiation therapy alone, which is limited in its ability to offer satisfactory treatment outcomes. I am encouraged that the data from the expansion part of our phase I study shows that NBTXR3 activated by radiation therapy could be a new option to improve therapeutic outcomes in this area. Continuing the development pathway into phase III will be an exciting step, and I am optimistic that what we have seen will continue." – Professor Christophe Le Tourneau, Curie Institute and Principal Investigator for the Study*

**Paris, France ; Cambridge, Massachusetts (USA) ; May 29, 2020** - NANOBIOTIX (Euronext: NANO - ISIN: FR0011341205 – the **"Company"**), a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced new data from the expansion part of its phase I trial, evaluating the potential of first-in-class NBTXR3 activated by radiation therapy to improve treatment outcomes for elderly patients with locally advanced head and neck cancer ineligible for chemotherapy or intolerant to cetuximab. The data were published as part of the virtual scientific program at the 2020 annual meeting of the American Society for Clinical Oncology (ASCO).

**Study 102: A phase I trial of hafnium oxide nanoparticles activated by radiotherapy in cisplatin-ineligible locally advanced HNSCC patients**
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J Clin Oncol 38: 2020 (suppl; abstr 6573). DOI: 10.1200/JCO.2020.38.15_suppl.6573.

Abstract Number: 6573

## Study Design

After reporting promising early signs of activity from the dose escalation part of its phase I trial evaluating the safety and feasibility of NBTXR3 activated by radiation therapy in elderly patients with locally advanced head and neck squamous cell carcinoma (HNSCC), the Company launched an expansion cohort to confirm results and observed trends with a larger population treated at the recommended dose. This part of the study is expected to recruit a total of 44 evaluable patients. To date, 40 patients have been recruited, 30 of whom are evaluable for efficacy and are included in the data presented at ASCO 2020.

## Topline Results

As previously announced, in the dose escalation part of the study NBTXR3 activated by radiation therapy was safe and well tolerated. The recommended phase 2 dose (RP2D) was determined to be 22% of baseline tumor

volume. Among 16 evaluable patients, injected lesion complete response rate was 56% and overall objective response rate was 69%.

Regarding the new, expansion part data, analysis of 40 patients dosed showed that NBTXR3 activated by radiation therapy remains safe and well tolerated. In terms of efficacy, for the 30 evaluable patients, investigators observed, at a median time of 5 months after NBTXR3 injection, an overall objective response rate of 83% and an overall complete response rate of 43% and objective response rate of the primary tumor (target lesion) of 83% with a complete response rate of the primary tumor of 60%. The safety profile was consistent with the dose escalation part and the efficacy data improved (i.e. an increase in overall objective response rate from 69% in the dose escalation part to 83% in the dose expansion part).

In the safety population (all treated patients, N=40), three serious adverse events (SAEs) related to NBTXR3 were observed (0.7% of all AEs), comprising one case each of: Grade 4 tumor hemorrhage also related to radiotherapy, Grade 3 mucosal inflammation and Grade 2 swollen tongue also related to the injection procedure. Two SAEs related to the injection procedure were reported (0.5% of all AEs), comprising: two cases of swollen tongue, of which one was Grade 2 and also related to NBTXR3, and one was Grade 4. The radiotherapy-associated safety profile was as expected with the most frequently occurring AEs being stomatitis and skin injury. Three deaths due to AEs related to radiotherapy and other causes were observed. Four other patients died of non-oncologic or non-toxicity-related reasons.

**Next Steps in Head and Neck Cancer**

The expansion part of the phase I trial will continue to recruit until reaching 44 evaluable patients. In parallel, subject to the FDA's pending review, the Company intends to globally launch a pivotal phase III trial. In the planned phase III trial, a futility analysis is expected 18 months after the first patient is randomized, and an interim analysis of progression-free survival (PFS) is expected at 24-30 months.

NBTXR3 for the treatment of locally advanced HNSCC patients who are not eligible for platinum-based chemotherapy received Fast Track designation from the FDA in February 2020. Fast Track designation is a process designed to facilitate the development and accelerate the review of drugs for serious conditions that have the potential to address unmet medical needs. The purpose is to expedite the availability of new treatment options for patients.

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## 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.

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.

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 has a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (initially expected to support 9 new clinical trials in the United States) to evaluate NBTXR3 across several cancer types.

## 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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