Nanobiotix: 2017 review and 2018 expected milestones

Paris, France and Cambridge, Massachusetts, USA, December 26, 2017 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, today provides a recap of its activities and achievements in 2017 and an overview of its anticipated 2018 milestones.

- Strong news flow anticipated for 2018
- Acceleration and expansion of clinical development
- First data showing strong potential of NBTXR3 lead product in high risk elderly H&N patients
- Progress in first European market approval but notified body requests more time to finalize technical evaluation
- Completion of recruitment of Soft Tissue Sarcoma PII/III
- Structuration of company to become a fully integrated pharma company
- €52M raised with two private placements
- From first data in new immuno-oncology program to FDA approval to start a first clinical trial combining NBTXR3 and anti-PD1 antibody

I - 2017 Review

Regulatory and premarket activities

- **CE mark progress, December update**

Nanobiotix, in accordance with the notified body for medical devices (LNE/G-MED), has followed a pathway for CE marking that involves two steps within Annex II: The conformity of the full quality assurance system and the product technical file.

As part of the Annex II process, LNE/G-MED audited Nanobiotix in October 2017 regarding the design, development, manufacturing and commercialization of the product. No major findings were identified by the auditors, which presumably puts the Company in a good position to obtain Annex II.

Regarding the technical file, LNE/G-MED recently informed us they would need a few more months to finalize the evaluation required for CE marking.

- **Medical Affairs activities**

Nanobiotix establihed in the second half of 2017 a strong international team of experienced medical science liaison officers to support the dissemination of knowledge and the use of NBTXR3 within the international medical community prior to approval. To support these developments, Nanobiotix recently opened two new affiliates in Europe, in Germany and in Spain.

- **Nanobiotix opens new manufacturing facility**

In November 2017, Nanobiotix expanded its manufacturing capabilities to increase its production capacities for the commercial launch and clinical trials needs. This new facility is located in the Villejuif BioPark, a scientific research and innovation center just outside of Paris, France. The new facility will supplement the existing capacities.

NBTXR3's development

- **Soft Tissue Sarcoma (STS) Phase II/III,** "Act.In.Sarc" pivotal trial (www.actinsarc.com)

March 2017, positive interim analysis: pre-planned interim analysis was based on the results of two-thirds of the patients included – 104 out of a total of 156 patients were analyzed. Based on the available safety and efficacy data, the Independent Data Monitoring Committee recommended the continuation of the ongoing Phase II/III trial of NBTXR3 in soft tissue sarcoma.

October 2017: Nanobiotix completed patient inclusion for the Phase II/III trial. The Company expects to present the results of this trial in Q2 2018.

- **Phase I/II head and neck trial in high risk elderly patients**

June 2017: Nanobiotix presented first results from its Phase I/II head and neck cancer trial with NBTXR3 at the American Society of Clinical Oncology's (ASCO) annual meeting.

> **Good safety and promising signs of efficacy and long-term control**: The results showed a very good safety profile for NBTXR3 with no Adverse Events (AEs) and no Serious Adverse Events (SAEs) in frail elderly patients with stage III/IV cancer, seven out of nine patients achieved a Complete Response at a 10% dose level or more. Patient follow-up showed a potential impact on long-term disease control.

July 2017, in light of the promising results, Nanobiotix filed a protocol amendment to include 44 additional patients. Up to 15 additional sites in Europe would be added for this expansion phase.

November 2017 Prof. Christophe Le Tourneau, the trial's Principal Investigator, presented an update during the Trends in Head and Neck Oncology conference (THNO), with a patient median follow up of 14.2 months, confirming the potential impact of NBTXR3 on the long-term response of the treatment.

- **Immuno-oncology Program**

Preclinical data presented at three major international conferences in 2017 demonstrating that NBTXR3 activated by radiotherapy could generate an adaptive antitumor immune response, turning "cold" tumors in "hot" tumors:

- American Association for Cancer Research (AACR) Annual Meeting 2017, Washington D.C
- "*Immunotherapy workshop - Incorporating Radiation Oncology into Immunotherapy*" co-sponsored by the American Society of Radiation Oncology (ASTRO), the National Cancer Institute (NCI) and the Society for Immunotherapy of Cancer (SITC), Bethesda
- Society for Immunotherapy of Cancer (SITC) Annual Meeting, National Harbor

November 2017, first human data presented at SITC showing that NBTXR3 could transform a cold tumor into a hot tumor in Soft Tissue Sarcoma. In November, Nanobiotix presented new clinical data confirming NBTXR3's significant potential role in immuno-oncology at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.

These data showed the potential of NBTXR3 to transform "cold" tumors into "hot" tumors. They showed that NBTXR3 activated by radiotherapy induces a different and significant adaptive immune pattern versus radiotherapy in patients with soft tissue sarcoma.

These clinical and preclinical data indicate that NBTXR3 could play a key role in immuno-oncology.

- **December 2017: FDA approved Nanobiotix' IND application for a study of NBTXR3 activated by Radiotherapy in combination with anti-PD1 antibody in lung, and head and neck cancer patients**

Nanobiotix will start in Q2 2018 a new phase I/II clinical trial with NBTXR3 activated by radiotherapy in combination with anti-PD1 antibody in the U.S. The multi-arm trial will include locoregional recurrent and/or metastatic lung, and head and neck cancer patients that are either anti-PD1 naïve or non responders at 12 weeks. The phase II portion of the trial will investigate the potential of NBTXR3 to transform anti-PD1 non-responders into responders and increase responses of anti-PD1 antibody in locoregional recurrent HNSCC amenable to re-irradiation.

Corporate and financial events

- **Nanobiotix appointed senior executive from pharmaceutical industry, as Chief Operating Officer**

At the beginning of 2017, Nanobiotix appointed Alain Dostie, an oncology industry veteran from the pharmaceutical industry, as Chief Operating Officer to oversee NBTXR3 product development and commercialization.

- **€52M raised with two private placements**

Nanobiotix realized two private placements in order to support the acceleration and the expansion of the development and commercialization plan and to expend its financial visibility. These operations opened the opportunity for Nanobiotix to welcome new European and U.S. qualified biotech investors. The cumulated amount of money raised is about €52.3 M.

II – 2018 Forthcoming news flow: selected milestones

2018 should be another year of growth for Nanobiotix with multiple new and ongoing projects!

- **First presentation of liver Phase I/II trial data (primary and metastasis) to be presented at ASCO-GI**
- **First patient recruitment in Phase I/II clinical trial in the US looking at the potential of NBTXR3 to transform anti-PD1 non responders into responders. The multi-arm trial will include recurrent and/or metastatic lung, and head & neck cancer patients**
- **Presentation of the results of Phase II/III STS, after last patient has been treated and the analysis is complete**
- **First market approval in Europe, CE marking**
- **Interim update from Phase I/II head and neck cancer trial with high risk elderly patients**
- **Additional news on other clinical trials and programs**

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About NBTXR3

NBTXR3 is an injectable aqueous suspension of hafnium oxide nanoparticles designed as an innovative therapeutic agent for the treatment of solid tumors, currently in clinical development by Nanobiotix.

Once injected intratumorally, NBTXR3 can deposit high energy within tumors only when activated by an ionizing radiation source, notably radiotherapy. Upon activation, the high energy radiation is physically designed to kill the tumor cells by triggering DNA damage and cell destruction and improve clinical outcomes.

Promising results indicate that NBTXR3 activity could be applicable across solid tumors triggering immunogenic cell death, leading to an immune response, reinforcing a local and potentially systemic effect, and contributing to transform “cold” tumors into “hot” tumors. NBTXR3’s major characteristics are represented by a high degree of biocompatibility, one single administration before and during the whole therapy and the ability to fit into current standards of radiotherapy care.

NBTXR3 entered clinical development in 2011 in a Phase I/II with patients suffering from advanced soft tissue sarcoma of the extremities and is currently in the final stages of its subsequent phase II/III. In parallel, it is currently being tested in numerous Phase I/II clinical trials with patients suffering from locally advanced squamous cell carcinoma of the oral cavity or oropharynx (head and neck), liver cancer (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.

About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late clinical-stage nanomedicine company pioneering novel approaches to the treatment of cancer. The Company’s first-in-class, proprietary technology, NanoXray, enhances radiotherapy energy with a view

to providing a new, more efficient treatment for cancer patients.

NanoXray products are compatible with current radiotherapy treatments and are meant to treat potentially a wide variety of solid tumors including soft tissue sarcoma, head and neck cancers, liver cancers, prostate cancer, breast cancer, glioblastoma, etc., via multiple routes of administration.

NBTXR3 is being evaluated in: soft tissue sarcoma (STS), head and neck cancers, prostate cancer, and liver cancers (primary and metastases). Additionally, head and neck cancer and rectal cancer trials led by Nanobiotix's Taiwanese partner, PharmaEngine, are underway in the Asia Pacific region.

The Company is also running research programs in immuno-oncology, with its lead product NBTXR3, which could have the potential to bring a new dimension to cancer immunotherapies.

Nanobiotix is listed on the regulated market of Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP). The Company's Headquarters are based in Paris, France, with a U.S. affiliate in Cambridge, MA.

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