Nanobiotix presented new clinical and pre-clinical data confirming NBTXR3's significant potential role in Immuno-Oncology at SITC Annual Meeting

- NBTXR3 activated by radiotherapy induces a significant adaptive immune pattern versus radiotherapy alone in patients with soft tissue sarcoma
- Patients treated with NBTXR3 and radiotherapy show a marked increase of PD1 and CD8 infiltration
- Preclinical data on different animal models confirm broad potential of NBTXR3 as a primer of the immune response
- Strong data to support the rational for the upcoming clinical trial in combination with check point inhibitors.

Paris, France and Cambridge, Massachusetts, USA, November 13, 2017 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, recently presented positive clinical and preclinical data from the ongoing immuno-oncology programs. These data were presented at the 32nd Annual Meeting of the Society for Immunotherapy of Cancer (SITC), held from November 8 to 12, 2017 in National Harbor, Maryland, USA.

Nanobiotix's lead product, NBTXR3, has a universal physical mode of action which is designed for the local destruction of tumors. In addition to the physical destruction of cancer cells, recently published data suggested that NBTXR3 generates immunogenic cell death which could trigger a specific immune response to attack tumors.

The new clinical data and pre-clinical data indicate that NBTXR3 could play a key role in oncology and could become a backbone of immuno-oncology.

The data Nanobiotix recently presented at SITC from its immuno-oncology programs included:

"Antitumor immunity in patients with locally soft tissue sarcoma treated with hafnium oxide nanoparticles and radiation therapy"[1] -- P 412

In this study, tumors from the ongoing two-arm Phase II/III clinical trial were examined both pre- and post-treatment in patients with locally advanced soft tissue sarcoma who had received either NBTXR3 with radiotherapy (more than 10 patients) or radiotherapy alone (more than 10 patients).

The results observed in the post-treatment examination of patients who received both NBTXR3 and radiotherapy showed a significant increase of CD8+ T cells and a marked increase of CD3+, PD-1 and CD103+ immune cell infiltration. In contrast, there was no difference observed between pre- and post-treatment examination when patients received radiotherapy alone.

Furthermore, a functional analysis of genes up-regulated in NBTXR3 plus Radiotherapy arm showed an enrichment of cytokines, immune checkpoints, T cell activation, and dendritic/macrophages markers.

These promising data confirm that NBTXR3 induces a specific adaptive immune pattern and brings substantial changes to the tumor immune profile in patients with soft tissue sarcoma. As such, it may convert the tumor immunologically and be effectively combined with immunotherapeutic agents across oncology.

These data strengthen the relevance of using NBTXR3 in combination with immune checkpoint inhibitors. In September 2017, Nanobiotix announced the Company's plan to conduct its first clinical trial with NBTXR3 in combination with immune checkpoint inhibitors in the U.S., with a multi-arm trial targeting a sub-population of advanced lung, and head and neck cancer patients.

"Transforming immunologically 'cold' tumor into 'hot' tumor with hafnium oxide nanoparticles and radiation therapy"[2] -- P 413

These in vivo pre-clinical studies explored the ability of NBTXR3 to bring substantial immune cell infiltrations in colorectal cancer and breast cancer models, and convert immunologically "cold" tumors into "hot" tumors.

In mice bearing CT26 tumors (murine colorectal cancer cells), a marked increase of cytokine content and immune cell infiltrates was observed with NBTXR3 and radiotherapy compared to radiotherapy alone.

In mice inoculated with 4T1 cells (murine breast cancer model) previously treated with NBTXR3 and radiotherapy, a marked increase of CD8+ was observed in tumors when compared to those in mice inoculated with 4T1 cells treated only with radiotherapy.

Data generated from colorectal and breast cancer tumor models suggest that NBTXR3 triggers immunogenic conversion of the tumor microenvironment regardless of the molecular characteristics of the tumor. These data confirm the broad potential of NBTXR3 as a primer of the immune response.

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About NANOBIOTIX's immuno-oncology research program

Many IO combination strategies focus on 'priming' the tumor, which is now becoming a prerequisite of turning a "cold" tumor into a "hot" tumor. Compared to other modalities that could be used for priming the tumor, NBTXR3 could have a number of advantages: the physical and universal mode of action that could be used widely across oncology, the one-time local injection and good fit within existing medical practice already used as a basis for cancer treatment, as well as a very good chronic safety profile and well-established manufacturing process.

After more than 18 months of development, the Company presented preclinical proof of concept demonstrating that NBTXR3 actively stimulates the host immune system to attack tumor cells.

Recently, Nanobiotix presented new translational data. Taken together, these non-clinical and preliminary clinical results confirm that NBTXR3 plus radiotherapy could efficiently prime an adaptive antitumor immune response, turning "cold" tumors in "hot" tumors. Additionally, these results suggest that the physically-induced response and subsequent immune activation triggered by the NBTXR3 treatment could be generic.

Results suggests that NBTXR3 with radiotherapy could transform tumors into an effective in situ vaccine, opening up very promising perspectives in the treatment of local cancer and metastases.

On top of the Company's core development activities, these findings could open new collaborations for NBTXR3 through combinations with other immuno-oncology drugs.

In September 2017, Nanobiotix announced its intention to start a new trial in the company's immuno-oncology (IO) program. The trial is aimed at expanding the potential of NBTXR3 to recurrent and metastatic disease.

About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late clinical-stage nanomedicine company pioneering novel approaches for 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 filed in August 2016 for market approval (CE Marking) in Europe for its lead product NBTXR3.

In 2016 the Company started a new preclinical research program 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 is based in Paris, France, with a U.S. affiliate in Cambridge, MA.

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This press release contains certain forward-looking statements concerning Nanobiotix and its business. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number D.17-0470 on April 28, 2017 (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.

This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country. At the moment NBTXR3 does not bear a CE mark and is not permitted to be placed on the market or put into service until NBTXR3 has obtained a CE mark.

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