



NANOBIOTIX ANNOUNCES FIRST POSITIVE HUMAN DATA SHOWING THAT NBTXR3 COULD BECOME A BACKBONE IN IMMUNO-ONCOLOGY

- Biomarker two-arm study in 26 Soft Tissue Sarcoma patients
- Data shows a specific, adaptive immune pattern triggered by NBTXR3 treatment
- Potential synergies with Immuno-oncology drugs including checkpoint inhibitors

Paris, France and Cambridge, Massachusetts, (USA) May 18, 2017 – [NANOBIOTIX](#) (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced its first set of clinical data from its immuno-oncology (IO) program, showing the potential ability of NBTXR3 to transform “cold” tumors into “hot” tumors.

Laurent Levy, CEO of Nanobiotix said, *“Being able to transform cold tumors into hot tumors is one of the most challenging and promising topics in oncology. This preliminary clinical data indicates that NBTXR3 could play a key role in unlocking this potential. Given NBTXR3’s universal type mode of action and good safety profile, NBTXR3 could change the treatment landscape in numerous solid tumor cancers.”*

Many tumors exhibit little or no response to therapies targeting the immune system and are considered “cold”. The explanation for the lack of response in its simplest form is a lack of immunogenicity. The ability of NBTXR3 to generate intratumoral immunogenic cell death (ICD) could be a key to significantly increase the number of patients who can engage their immune system to fight their cancer.

To undertake this research, Nanobiotix used the available patient samples from its more advanced indication of soft tissue sarcoma -- a typical “cold” tumor. These findings demonstrated that NBTXR3 plus radiotherapy induces a specific adaptive immune pattern, which could potentially contribute to converting a “cold” tumor into a “hot” tumor. In this study, radiotherapy alone did not show any impact on triggering adaptive immune response.

Key Results

Specific adaptive immune pattern induced by NBTXR3 when exposed to radiation therapy in Soft

Tissue Sarcoma (STS) patients (#e14615)

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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 (14 patients) or radiotherapy alone (12 patients).

The results observed in the post-treatment examination of patients who received both NBTXR3 and radiotherapy, showed a significant increase of immune cell infiltration (CD3+, CD8+). In contrast, there were no differences observed between pre- and post-treatment examination where patients received radiotherapy alone.

Similarly, patients who received NBTXR3 plus radiotherapy were found to have an increased immunoscore post-treatment, compared to those who received radiotherapy alone.

The upregulation of pan-immune gene expression and specifically, the expression of adaptive immunity genes between pre- and post-treatment, was pronounced in the post-treatment results of patients who received NBTXR3 plus radiotherapy compared to those who received radiotherapy alone.

Furthermore, a functional analysis of upregulated genes in NBTXR3 plus radiotherapy showed a specific enrichment of cytokine activity (IL7, IFNA, IL16, IL11, IFNG), adaptive immunity (RAG1, GZMA, TAP1, TAP2, TBX21, STAT4, IFNG, LCK, LTK, CD37, CD22) and T-cell receptor signaling pathway (CD28, CTLA4, CD274, BTLA, TIGIT, CD40LG, CD5, CD3E, ZAP70).

The initial data suggests NBTXR3's potential as an IO agent that could, on its own, trigger a specific immune response against the tumor. A number of upregulated genes correspond to existing or promising IO targets, enabling potential combination of NBTXR3 with therapeutic approaches, like products targeting PD1, PDL1, CTLA4, etc. This data requires confirmation in additional studies.

NBTXR3 competitive positioning in IO

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.

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

About NBTXR3

Nanobiotix's lead product, NBTXR3, is a first-in-class radio-enhancer nanoparticle designed for direct injection into cancerous tumors. It has been engineered to increase the dose and efficacy of radiotherapy without increasing toxicity or causing damage to surrounding healthy tissues. NBTXR3 is currently in late-stage clinical development as a single agent.

Worldwide clinical development of NBTXR3 now includes trials across 7 patient populations:

- **Soft Tissue Sarcoma (STS)**
Phase I/II trial completed
Phase II/III "Act.in.Sarc." global trial (including EU, South Africa and Asia-Pacific region)
- **Head and Neck Cancer**
Phase I/II trial in France and Spain; NBTXR3 + Radiotherapy alone
Phase I/II trial by PharmaEngine in Asia-Pacific; NBTXR3 + Radiotherapy & Chemotherapy
- **Prostate Cancer**
Phase I/II trial in the U.S
- **Liver Cancers**
Phase I/II Hepatocellular Cancer trial in France
Phase I/II Liver Metastases trial in France
- **Rectal Cancer**
Phase I/II trial by PharmaEngine in Asia-Pacific

First market approval has been filed in the EU.

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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 provide 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 has filed in August 2016 for market approval (CE Marking) in Europe for its lead product NBTXR3.

The Company started in 2016 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 Headquarter is based in Paris, France. Affiliate in Cambridge, United States.

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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.