



Nanobiotix plans to conduct its first clinical trial with NBTXR3 in combination with immune checkpoint inhibitors in the U.S.

- Multi-arm trial targets sub-population of advanced lung, and head and neck cancer patients
- Medium term objective is to transform non-responders into checkpoint inhibitor responders while improving patient benefits
- Trial aims to evaluate the ability of NBTXR3 to generate an abscopal effect
- Expands the potential for NBTXR3, including recurrent or metastatic disease
- Trial should start with combining NBTXR3 with any approved checkpoint inhibitors in head and neck squamous cell carcinoma or non-small cell lung cancer

Paris, France and Cambridge, Massachusetts, USA, September 28, 2017 – [NANOBIOTIX](#) (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, announced today 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.

The trial would target recurrent head and neck, and metastatic lung cancer patients. Studies indicate that the vast majority of oncology patients do not respond to checkpoint inhibitors.

Nanobiotix’s plan for this U.S.-based trial is to evaluate its lead product, NBTXR3, in combination with immune checkpoint inhibitors, with the aim of unlocking their vast potential to convert refractory patients into responders.

Elsa Borghi, Nanobiotix’s Chief Medical Officer commented: *“The immunomodulatory effects of NBTXR3 have the potential to transform non-responders into responders. This approach could be practice-changing, as it addresses unmet medical needs through directed tumor in situ vaccination.”*

For the past decade, there has been excitement around immuno-oncology agents’ capacity to boost the immune system’s response, priming it for an active attack against tumor cells. The response to checkpoint inhibitors in so-called “hot” tumors, infiltrated by T-cells and characterized by an inflammatory profile, has been striking with long-lasting clinical benefits in many cancer patients.

However, many tumors exhibit little or no response to therapies targeting the immune system and are considered “cold”, due to a lack of immunogenicity.

According to published data, only 15 to 20% of non-small-cell lung cancer patients (NSCLC), and 13 to 22% of head and neck squamous cell carcinoma patients (NHSCC) respond to immunotherapy treatments.

Moreover, treatment using checkpoint inhibitors is generally not effective against all tumor types (“cold” tumors devoid of T-cell saturation, PD-1/PDL-1 blockage cannot drive an anti-cancer response).

The physical mode of action and subsequent cell death generated by NBTXR3 induce a different immunogenicity compared to radiotherapy and chemotherapy. This could be the key to significantly increasing the number of cancer patients who can benefit from immuno-oncology strategies.

As Nanobiotix reported earlier this year at ASCO 2017, NBTXR3 activated by radiotherapy was shown to induce a specific adaptive immune pattern that could potentially convert a non-responder into an immune-responsive patient receptive to treatment with checkpoint inhibitors.

On top of NBTXR3’s core developments as a single agent across seven oncology indications, Nanobiotix’s Immuno-Oncology combination program opens the door to new developments, potential new indications, and important value creation opportunities.



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 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.

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

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

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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