



Small but heading for the big time

Nanobiotix receives first approval to start phase II/III registration trial in soft tissue sarcoma in Europe

Paris, France, 16 October, 2014 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announced today that it has received approval from the French National Security Agency for Medicines and Health Products (ANSM) to start its Phase II/III registration trial of its lead product, NBTXR3, in patients with locally advanced Soft Tissue Sarcoma (STS).

Patients with locally advanced STS have very limited therapeutic options. Today, a standard treatment of care before surgery is radiotherapy aiming to reduce the tumor volume. Thereafter surgery is still required to remove the tumor. But despite of radiotherapy, a considerable proportion of patients with advanced tumors that cannot be resected in their entirety. The remaining tumor mass promotes the further development of the disease resulting in a poor prognosis for the patient.

NBTXR3 has the potential to provide a significant clinical benefit by improving radiotherapy efficacy, destroying locally advanced tumors more efficiently and to improve the quality of surgery enabling a more complete removal of the tumor.

This international multi-center pivotal study will start in France and then be conducted in around 25-30 sites throughout Europe once further authorizations are received. This pivotal trial is expected to be the final step before registration in Europe (CE mark) and should be --completed towards the end of 2016. In the Asia-Pacific region, as announced recently, PharmaEngine intends to participate in this pivotal study by opening clinical sites in several countries.

In parallel, Nanobiotix is establishing industrialization, market access and reimbursement strategies for NBTXR3 to prepare for a potential product launch at the end of 2016.

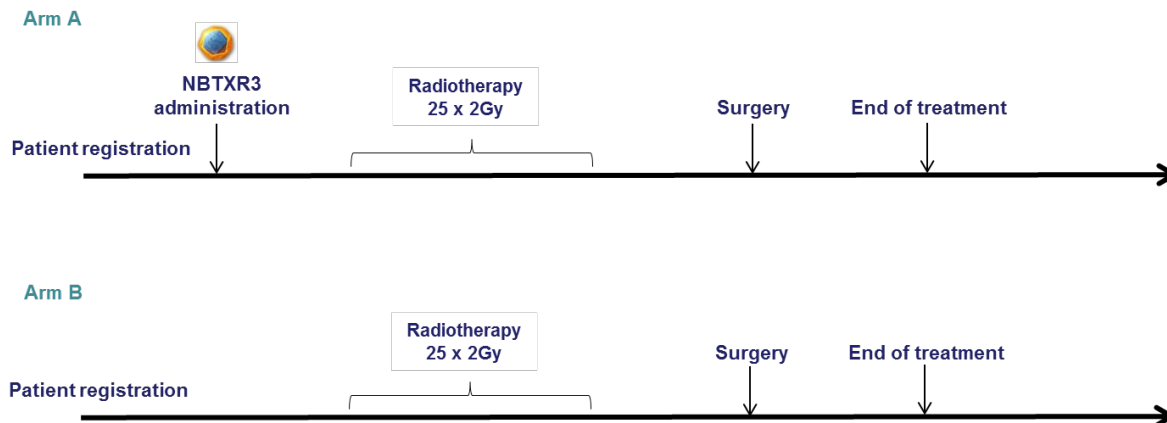
Laurent Levy, CEO of Nanobiotix commented: *“Following the ASCO results, this approval is the second most important step we have accomplished this year as it launches the last clinical phase before potential market authorization. We believe our product, NBTXR3 will offer meaningful clinical benefit for patients with advanced sarcomas where there are serious unmet medical needs.”*

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Notes to Editors

About the Phase II/III registration Trial of NBTXR3 in STS

A multi-center randomized, open-label, two-arm Phase II/III trial in patients with locally advanced soft tissue sarcoma of the extremity and trunk wall. Patients in the experimental treatment arm (Arm A) will receive an intratumoral injection of NBTXR3 followed by radiotherapy and surgery. Patients in the control arm (Arm B) will be treated with radiotherapy alone followed by surgery only. It is expected to enroll approximately 180 patients to have 78 evaluable patients in each arm.



Study design

The primary objective of this study is to increase the pathological complete response rate (pCR) of intratumoral injection of NBTXR3 activated by external beam radiation therapy (EBRT), versus EBRT alone in patients with locally advanced STS of the extremity and trunk wall.

Secondary objectives are to assess the safety profile of NBTXR3 activated by radiotherapy (incidence of early and late adverse events), to compare the objective response rate (ORR), tumor volume changes after NBTXR3 and carcinological resection rates, and to evaluate limb amputation rates.

Exploratory objectives are to assess the tumor response, to evaluate the time-to-local recurrence, Local Recurrence Rate (LRR) at 12 months and to evaluate the time-to-distant recurrence and Distant-Recurrence Rate (DRR) at 12 months.

Based on the results of the Phase I pilot trial, the recommended NBTXR3 volume for the pivotal study is equivalent to 10% of the tumor volume. Hence, the injected amount of NBTXR3 will be based on each patient's tumor volume as determined by MRI.

An interim efficacy analysis will be performed once two-thirds of patients have been recruited, it is expected mid 2016. An Independent Data Monitoring Committee (IDMC) will be in charge of the reviewing the formal statistical interim analysis, to ensure the safety of all patients enrolled in the study, the quality of the data collected and the continued scientific validity of the study design.

About clinical trials in Europe

In Europe clinical development of a new medical device is normally conducted in two phases, pilot and pivotal studies, which is supposed to lead to the European CE marking from the Healthcare Regulatory Agencies.

Usually, in the pilot phase, the goal is to establish medical device safety and to assist in design of the pivotal trial. Medical device pilot or feasibility studies are generally limited to a small cohort of patients at one or two sites.

After establishing that the medical device is safe in this pilot group of patients, the pivotal trial is conducted to generate data to demonstrate that the medical device is safe and effective, for a defined intended use, within a certain patient population.

For the record, NBTXR3 has been classified in the EU as class III medical device. In the US, it has been classified as a drug by the Food and Drug Administration (FDA).

About NBTXR3 in Soft Tissue Sarcoma (STS)

STS are cancers arising from different types of tissues such as fat cells, muscles, joint structures and small vessels etc. In resectable cases, surgery is the only potentially curative treatment and constitutes the basis to achieve prolonged survival.

Nevertheless, a considerable proportion of patients present with locally advanced primary or relapsed tumors and cannot be resected with clean margins. These patients with big tumors are threatened with amputation for complete tumor removal. Progress of surgical techniques and the use of pre-operative radiotherapy have improved the disease outcome. However local and distant failures are frequently observed.

There is strong evidence (scientific literature) that supports the importance of local control of tumor in patients with locally advanced STS. Indeed, achieving local control in these patients presenting with locally advanced disease is a determinant factor to improve disease free survival and overall survival. This is not surprising. Similar outcome is observed for other cancers.

Patients with high risk STS have few therapeutic options. Innovative treatments aimed at optimizing cancer cell killing and the surgical feasibility are needed.

NBTXR3 is the first product of the NanoXray portfolio to reach clinical development. The product comprises nanoparticles which can be injected directly into cancer cells.

Treatment with NBTXR3 nanoparticles and radiotherapy in locally advanced STS aims to destroy tumors more efficiently, to facilitate surgery and enable complete malignant tissue extraction during surgery.

NBTXR3 is a selective radioenhancer. The injected nanoparticles penetrate tumor cells and when exposed to radiotherapy make feasible the deposition of a high energy dose within the cancer cell, increasing cell killing and thus improving resectability and disease outcome.

Potential indications for this product include soft tissue sarcoma, head and neck cancer, liver cancer, glioblastoma (a specific form of brain cancer), rectal and prostate cancer.

About NANOBOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a clinical-stage nanomedicine company pioneering novel approaches for the local 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 a wide variety of cancers (Soft Tissue Sarcoma, Breast Cancer, Liver Cancer, H&N cancer, Glioblastoma, Prostate) via multiple routes of administration.

Nanobiotix's lead product NBTXR3, based on NanoXray, is currently under clinical development for soft tissue sarcoma and locally advanced head and neck cancer. The company, based in Paris, France, has partnered with PharmaEngine for clinical development and commercialization of NBTXR3 in Asia.

Nanobiotix is listed on the regulated market of Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP).

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