Small but heading for the big time

Nanobiotix expands Soft Tissue Sarcoma pivotal clinical trial across Europe and beyond, according to plan

Paris, France, May 11, 2015 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces the expansion of the pivotal phase II/III trial for NBTXR3 in Soft Tissue Sarcoma (STS). This trial is the final step before registration (CE mark).

- European expansion to four countries; 12 centers already open, 10 patients included in the past 30 days
- Submission ongoing in other European countries
- Expansion beyond Europe into Asia and North America via Canada

Laurent Levy, CEO of Nanobiotix said: "*Nanobiotix's global clinical development for NBTXR3 is running according to plan and anticipated schedule in every indication. The STS study is expanding in a dynamic way; during our recent investigators' meeting, in parallel with the ESTRO conference 2015, we gathered more than 80 trial participants together!*"

European expansion

The pivotal phase trial was launched following positive phase I results presented at ASCO 2014, which provided NBTXR3 proof of concept data. This international multi-center pivotal study is expected to be completed towards the end of 2016 (156 patients) with interim results in mid-2016 (104 patients). The results will mark the last step required before product registration (CE mark) which is anticipated towards the end of 2016.

The trial is already running in clinical centers of excellence in four European countries so far (France, Belgium, Spain, Hungary) and clinical authorization requests are ongoing in other European countries. This is in line with Nanobiotix's strategy to broaden the number of trial sites up to 25-30.

Patient recruitment rate is increasing in opened centers; in the past 30 days, 10 patients have been recruited.

Beyond Europe

Nanobiotix's Taiwanese partner PharmaEngine which joined the pivotal trial to accelerate NBTXR3's development in the Asia-Pacific Region, will develop the trial in several Asian countries.

Clinical request has also been requested for this NBTXR3 pivotal trial in Canada, in line with Nanobiotix's strategy for North America.

This ongoing expansion is a critical step in the development plan for the registration of Nanobiotix's lead product, NBTXR3.

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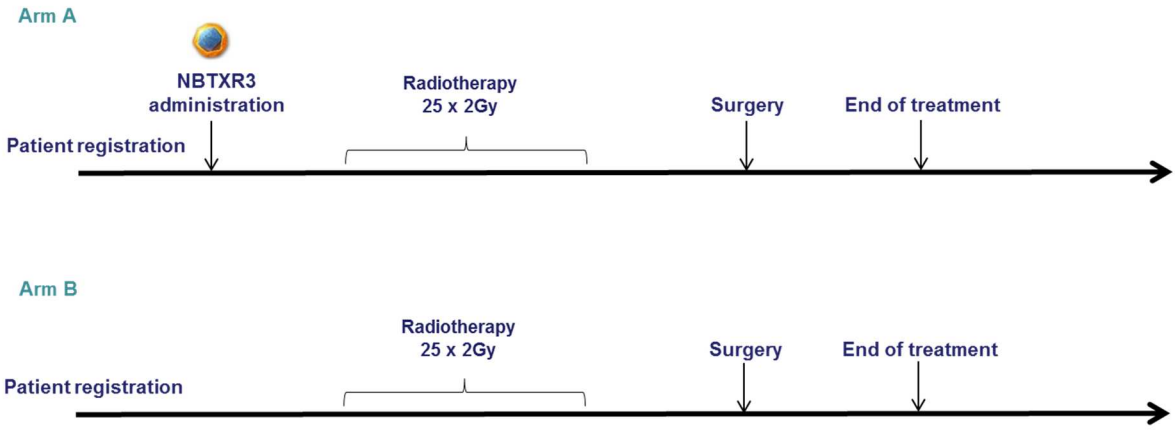
About the Phase II/III registration Trial of NBTXR3 in STS

The trial will compare the antitumor activity of NBTXR3 (administered by intratumoral injection) and radiotherapy compared with radiotherapy alone. Patients in both treatment arms will have a regular protocol which means five weeks of radiotherapy, followed by surgical resection of the tumor.



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.

For more information:
https://clinicaltrials.gov/ct2/show/NCT02379845?term=nbtxr3&rank=3

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.

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.

About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late 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 potentially a wide variety of cancers including Soft Tissue Sarcoma, Head and Neck Cancer, Liver Cancers, Prostate Cancer, Breast Cancer, Glioblastoma, etc., 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 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). The company, based in Paris, France, opened an affiliate office in the Boston area of the United States in September 2014.

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