Small but heading for the big time

Nanobiotix's Soft Tissue Sarcoma pivotal trial progressing well as planned: already 7 countries and 29 sites opened

Paris, France, November 13, 2015 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces the dynamic expansion of its pivotal phase II/III trial for NBTXR3 in Soft Tissue Sarcoma ("act.in.sarc" study) in 29 sites in 7 countries. The patient recruitment rate is increasing in line with the Company's expectations.

The international multi-center pivotal study (phase II/III) began end of 2014 in France. By June 2015, the trial was running in 12 European clinical centers of reference in France, Belgium, Spain and Hungary.

Three additional countries (Poland, Romania and South-Africa) and 17 additional clinical centers are now involved. Clinical authorization requests are ongoing in Canada and other Asia-Pacific and European countries.

This study is expected to be the final step before CE mark which is anticipated towards the end of 2016.

Elsa Borghi, CMO of Nanobiotix, commented: "*We are delighted with the growing dynamism of the study and the enthusiasm of our clinicians and other partners. NBTXR3 has the potential to significantly improve the efficiency of radiotherapy treatments across oncology indications, and the "Act.in.sarc" study could be the first step towards the generalization of the technology."*

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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. 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 tumor shrinkage, cell killing and thus improving resectability of the tumor with wide margins and disease outcomes.

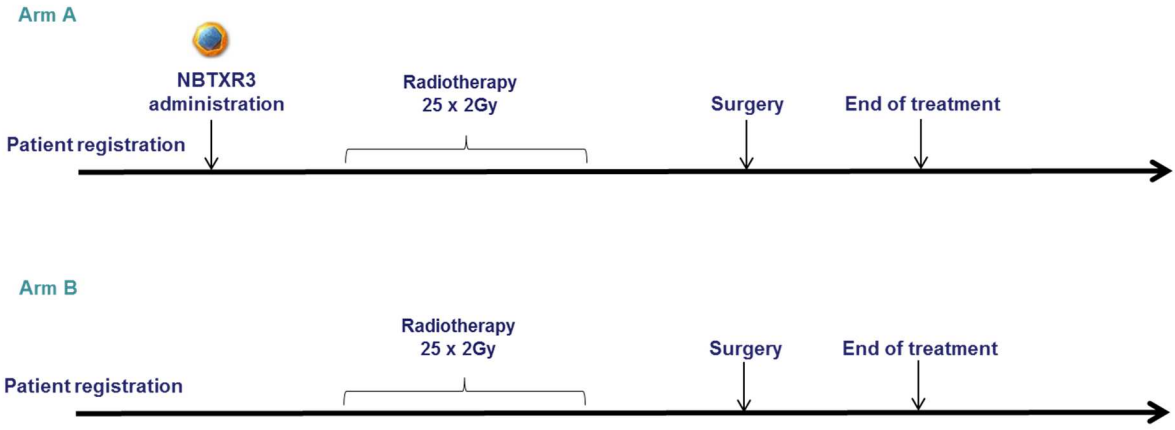
Expected benefits for patients:

- Increase of the quality/success of surgery
- Better local control expected: lower rate of local relapse
- Expected impact on distant metastasis development
- Decrease of need of adjuvant treatment, resurgery, reconstruction surgery or palliative treatment
- Increase mobility, functionality, quality of Life

http://www.actinsarc.com/

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

The randomized trial will measure the antitumor activity of NBTXR3 (administered by intratumoral injection) and radiotherapy compared with radiotherapy alone. Patients in both treatment arms (78 in each arm) will have a regular protocol which means five weeks of radiotherapy, followed by surgical resection of the tumor.



An interim efficacy analysis will be performed once two-thirds of patients have been recruited. 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: Clinical trial.gov

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, locally advanced Head and Neck Cancer, Rectum cancer (PharmaEngine) and Liver cancers. 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 Headquarter is based in Paris, France. Affiliate in Cambridge, United States.

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