Nanobiotix announces submission for first market approval of lead product NBTXR3 in Europe

CE Mark filing based on current level of scientific and clinical evidence

Phase II/III clinical trial in Soft Tissue Sarcoma progressing well towards interim data readout with almost 2/3 of the patients randomized

Paris, France and Cambridge, Massachusetts, USA September 13, 2016 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, has filed for market approval (CE Marking) in Europe for its lead product, a first-in-class radio-enhancer, NBTXR3.

The CE Marking submission package is in particular based on current level of evidence generated in the Act.In.Sarc registration trial for treatment of locally-advanced soft tissue sarcoma (STS) and other NBTXR3 clinical trials. The submission has been made in parallel with the continuation of the Act.In.Sarc study and the wider clinical development of NBTXR3 in different cancer indications.

The company filed for CE mark on August 23, and received the confirmation from Gmed (the french notified body), that the evaluation will start this month. The latest guidance given by the notified body for review up to potential CE marking is at least 9 months.

Laurent Levy, CEO of Nanobiotix, commented, "*This first market approval of NBTXR3 in Europe, is a major step for Nanobiotix, the fruit of more than 10 years of research and development. Recruitment has been a little slower than expected in STS clinical trial but overall we are progressing well in our global plan. With this filing we are closer to helping patients every day in hospitals.*"

Interim analysis readout of the Act.In.Sarc study

The Act.In.Sarc study is a global, randomized Phase II/III multi-center pivotal trial evaluating NBTXR3 in combination with radiotherapy before surgery in comparison to the current standard of care, radiotherapy alone, prior to surgery. 156 patients are expected to be included in the study. To date, 116 patients have been recruited and 92 patients randomized across 39 sites in 13 countries.

Nanobiotix plans to release the conclusion of the interim analysis conducted by an independent committee of experts in the coming months. The independent committee of experts will review (i) the data related to the primary endpoint (Complete Pathological Response Rate), ensure (ii) the safety of all patients enrolled in the study, (iii) the quality of the data collected, and (iv) the continued scientific validity of the study design once two third of the patients (104 patients) have been treated. This analysis will be performed four months after the 104th patient has been randomized (time to complete treatment plus readout).

The Company expects to complete patient enrollment of the Act.In.Sarc study in the 2nd quarter 2017.

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About NBTXR3 in Soft Tissue Sarcoma (STS)

STS are cancers arising in 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. Patients with high risk STS have few therapeutic options.

A considerable proportion of patients present with locally advanced primary or relapsed tumors 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 in scientific literature that supports the importance of local control of tumor in patients with locally advanced STS. Indeed, achieving local control, cellular destruction and good surgery in these patients presenting with locally advanced disease are determinant factors to improve disease free survival and overall survival. Similar outcome is observed for other cancers.

Innovative treatments aimed at optimizing cancer cell killing and the surgical feasibility are needed.

NBTXR3, is a first-in-class nanoparticle radio-enhancer designed for direct injection into cancerous tumors and is engineered to increase the dose and efficacy of radiotherapy without increasing toxicity or causing damage to surrounding healthy tissues. NBTXR3 has the potential to improve radiotherapy efficacy by destroying locally advanced tumors more efficiently, improving the chance of full tumor resection.

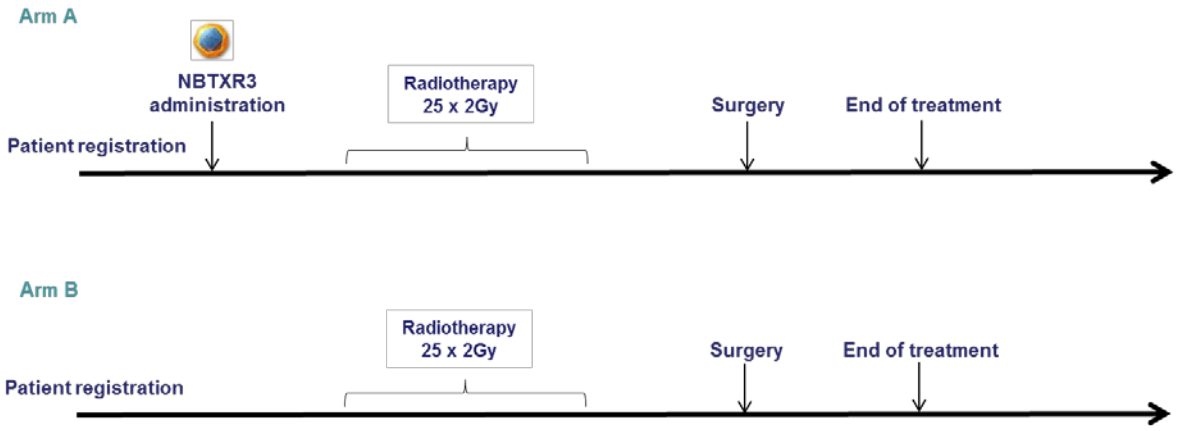
Treatment with NBTXR3 nanoparticles and radiotherapy in locally advanced STS aims to destroy tumors more efficiently, to facilitate surgery and enable complete malignant tissue extraction during surgery.

NBTXR3 is a 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.

For more information, please visit 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.



Primary Outcome Measures:

- Pathological Complete Response Rate (pCRR)

Secondary Outcome Measures:

- Incidence of early and late TEAE, post-TEAE, SAE and laboratory abnormalities (NCI CTCAE V4.0)
- Objective Response Rate (ORR) by Imaging (MRI) according to RECIST 1.1
- Tumor volume changes (theoretical tumor volume estimated as: Lenght x Width x Depth
- Resection Margins (R0, R1, R2)
- Limb amputation rate

For more information: https://clinicaltrials.gov/ and http://www.actinsarc.com/

About NANOBIOTIX:

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 solid

tumors including soft tissue sarcoma, head and neck cancers, 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, head and neck cancer, prostate cancer, rectal cancer (PharmaEngine) and liver cancers (HCC and liver metastases). 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.

For more information, please visit www.nanobiotix.com

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