Phase I Independent Data Monitoring Committee confirms good safety of NBTXR3 in the first group of patients with advanced Soft Tissue Sarcoma

Paris, France, November 13 2012 – Nanobiotix (Euronext: NANO / ISIN: FR0011341205), announced today that the Independent Data Monitoring Committee (IDMC) has reviewed the data of the first 6 patients treated in the phase I Study with the lead product NBTXR3 for the treatment of advanced Soft Tissue Sarcoma of the extremity. Based on the review of the safety data, the IDMC has unanimously recommended continuing the enrollment in the study according to the protocol. This trial is realized in the Institut Gustave Roussy, France.

“This milestone is crucial for NANOBIOKITIX” says Laurent Levy, CEO and co-founder of Nanobiotix. “It is in accordance with our expectations concerning our NanoXray products’ risk profile. After our successful IPO, we are happy to deliver this first milestone to all our investors and subscribers who have had confidence in the company. We intend to continue to deliver with our breakthrough technology to bring those products to patients rapidly and efficiently. This initial step is “derisking” our approach and gives us confidence to expend the clinical development to different indications.”

The IDMC consists of 3 independent members and has the responsibility of ensuring the safety of all patients enrolled in the study, the quality of the data collected and the continued scientific validity of the study design. The IDMC has reviewed the data of the first group of patients, focusing on patient’s safety and tumor surgery feasibility.

The clinical trial evaluates the following endpoints:

- Primary endpoints
  - Feasibility of the injection of NBTXR3 and its activation by radiotherapy in small and big tumors
  - Safety profile of NBTXR3 and its activation by radiotherapy
- Secondary endpoints
  - Tumor response to NBTXR3 activated by radiotherapy, in terms of cancer cell killing
  - Tumor downsizing and carcinologic surgery feasibility with NBTXR3 activated by radiotherapy (medical imaging)
  - Kinetic profile of NBTXR3 in the body

In this first group of patients, all the primary endpoints were reached, NBTXR3 demonstrated good safety and surgery was feasible with limb preservation in all patients.

The IDMC interim safety analysis found no evidence of local or general toxicity and accordingly the study is continuing. Based on their analysis, the committee has recommended starting the second group of patients without protocol amendments.

“The safety data from the first stage of the Phase I study met our expectations and confirms the positive safety data from our non-clinical studies results” said Dr. Elsa Borghi, Nanobiotix Medical Director. “A first milestone has been achieved in Nanobiotix’ mission to address the medical need in
patients with advanced tumors at high risk. We look forward to the next steps for NBTXR3 and remain confident in its potential to provide a new and important therapeutic option for patients with cancers.”

The trial is a prospective, open-label, dose-escalation and single arm study. NBTXR3 is administered to the patients by a single intra-tumor injection, followed by standard radiotherapy as pre-operative treatment. This pre-surgical treatment aims at shrinking the tumor or rendering possible the extraction of the whole malignant tissue, i.e. all cancer cells are resected. After completion of the regular treatment procedure, the patients will undergo the soft tissue sarcoma surgery. The primary tumor tissue will then be available for the evaluation of the cancer cell killing.

Patients’ candidates for this new modality of treatment are selected by the Sarcomas and Mesenchymal Tumors Committee of the Institut Gustave Roussy, which represents a highly specialized medical group for sarcoma care for more than 500 newly diagnosed patients per year.

About NBTXR3

NBTXR3, the lead compound of Nanobiotix’s NanoXray product pipeline, is a nanoparticle formulation of hafnium oxide crystals for the local treatment of tumors to enhance the efficacy of radiotherapy. NBTXR3 has been classified in the EU as class III medical device and is currently being tested in a European Phase I trial to establish feasibility and safety of NBTXR3 in patients with advanced soft tissue sarcoma. Further clinical trials are in preparation in Europe, in Asia-Pacific (through the PharmaEngine partnership) and in the US, where NBTXR3 is classified as a drug.

Additional information on the Company’s NBTXR3 clinical study may be found at www.clinicaltrials.gov / registration number RCB 2011-A00342-39.

About IDMC

The Independent Data Monitoring Committee (IDMC) consists of independent oncology surgeon, radiation oncologist and statistician and has the responsibility to check the data of the phase I study at regular intervals. The IDMC has the authority to recommend Nanobiotix changes to the study, to temporarily halt the patient enrollment, to discontinue or to continue the trial as planned. The members of the IDMC do not participate in the trial.

About NANOBIOTiX— www.nanobiotix.com

Nanobiotix, pioneer and leader in nanomedicine, has developed a revolutionary concept dedicated to the local treatment of cancer. Nanobiotix is focused on the development of NanoXray, a pipeline of patented products, which are based on the physical mechanism of action of the nanoparticles interacting with X-rays and maximizing radiation effect into tumor cells. NanoXray products enhance the efficacy of the radiotherapy in the tumor without increasing healthy tissues damages. NanoXray products can be used with existing standard radiation equipments available in almost every hospital worldwide.

Nanobiotix is a spin-off of the State University of New York (SUNY) at Buffalo that was incorporated in 2003 and has been primarily funded by leading European venture capital firms. The company has more than 30 employees and is based in Paris, France. Nanobiotix’ objective is to enhance its leading position in the nanomedicine field on the main oncology markets. Its pipeline of universal products enable to target the major indications of cancers (breast cancer, prostate cancer, lung cancer...),
leading to a potential market of several billion dollars. Thanks to the physical based mechanism of action of its nanoparticles, Nanobiotix brings out a unique business model with much lower risk than classic drug development, enabling a faster and less expensive time to market.


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