



For immediate release

Nanobiotix Starts Clinical Trial with Lead Product NBTXR3 *A Completely New Cancer Treatment to Be Tested in Patients with Soft Tissue Sarcoma*

Paris, France - September 13th 2011 - Nanobiotix, a company developing novel cancer nanotherapeutics, announced today that its lead compound NBTXR3 has received the formal authorization from the French Medicine Agency, AFSSAPS*, to start the first clinical trial[†].

27 patients diagnosed with soft tissue sarcoma will be enrolled in the Phase I study and will receive NBTXR3 as an intra-tumoral injection with radiotherapy prior to surgery (first-line treatment) (www.clinicaltrial.gov). The primary endpoints of the clinical trial are the feasibility of NBTXR3 administration and safety. Preliminary data are expected by the end of 2012.

The trial is a prospective, open-label, dose-escalation, single arm, non-randomized trial. NBTXR3 will be administered to the patients prior to surgery by a single intra-tumoral injection followed by standard radiotherapy procedure. After completion of the regular treatment procedure, the patients will undergo surgery to resect the soft tissue sarcoma. Along with the safety and feasibility endpoints, the primary tumor tissue will then be available for the evaluation of the pathological response rate.

Further clinical trials are in preparation in Europe and in the US. NBTXR3 has been classified in the EU as class III medical device. In the US, it has been classified as a drug by the FDA.

NBTXR3, the most advanced compound of Nanobiotix' NanoXray pipeline, is intended to enhance the local destruction of the tumor mass during radiotherapy. NBTXR3 is a nanoparticle consisting of hafnium oxide crystals. Once injected into the tumor, NBTXR3 accumulates in the cancer cells. Due to the physical properties of hafnium oxide, the particles emit huge amounts of electrons upon radiation. This leads to the formation of radicals within the tumor cell, which in turn damage the cancer cells and cause their targeted destruction. NBTXR3 particles are inert and emit electrons only during their exposure to radiotherapy. As a result, the destructive power of standard radiation therapy could be locally and selectively enhanced within the tumor cells.

* Agence Française de Sécurité Sanitaire des Produits de Santé

† Clinical trial, registration number RCB 2011-A00342-39

“This approach has the potential to solve one of the biggest problems in treating radio-resistant tumors with radiotherapy: how to increase the dose inside the tumor without harming the surrounding healthy tissue,” said Prof. Bo Lu, radiation oncologist and Director of the Molecular Radiation Biology Division, Thomas Jefferson Hospital, USA. *“Therefore, it may represent a breakthrough in radiotherapy where no major achievements have been made for the last decades.”*

“This is a key milestone for Nanobiotix. Developed in close collaboration with leading oncologists and radiotherapists, NBTXR3 is the first product from our NanoXray pipeline to enter clinical development,” said Laurent Levy, PhD, CEO and co-founder of Nanobiotix. *“With our NanoXray products, we hope to address the medical need to improve the efficacy of radiotherapy in tumors that can be resistant to irradiation. We are confident that the importance of nanomedicine will increase with NBTXR3 being the first-in-class product for the local control of solid tumors.”*

Local treatment of malignant tumors is a cornerstone of cancer therapy. The standard treatments are surgery and radiotherapy, either as a stand-alone treatment or in combination. Radiotherapy has been widely used across most oncology indications for decades. About 50 to 60% of all cancer patients undergo radiotherapy treatment as part of existing treatment guidelines. All NanoXray products are compatible with these guidelines and do not require changes of surgery and radiotherapy procedures. Moreover, NanoXray products can be used with any existing standard radiation equipment available in almost every hospital world-wide.

ABOUT NANOXRAY

Radiotherapy is used to treat about 50 to 60% of all cancer patients. It is known to be an effective treatment, but its efficacy is counteracted by the side effects in healthy tissue as the radiotherapy beam always needs to cross healthy tissue to reach the tumor. Radiotherapy therefore has a relatively narrow therapeutic window with a considerable need for improvement. Nanobiotix has developed a new class of therapeutics based on nanoparticles called [NanoXray](#) therapeutics. They consist of inert nanoparticles designed to enter tumor cells. Upon activation by a standard dose of radiation, NanoXray therapeutics release a tremendous amount of electrons, leading to the formation of radicals that destroy the cancer cells. As shown in preclinical experiments, this release should be restricted to the tumor as the particles are delivered selectively to the tumor site. The surrounding healthy tissue is not affected and receives the normal radiation dose as in standard radiotherapy. Nanobiotix' goal is to significantly enhance the efficacy of radiotherapy within the tumor and to improve the clinical outcome of local treatment.

ABOUT NANOBIOTIX – www.nanobiotix.com

Nanobiotix is a Paris, France, based nanomedicine company dedicated to the development of new cancer treatments. The company combines the advantages of nanotechnology and biotechnology. Nanobiotix is a spin-off of the State University of New York at Buffalo and was incorporated in 2003. It is funded by leading European venture capital firms (Matignon Technologies, OTC Asset Management, Cap Decisif, Amorcage Rhone-Alpes, CIC Vizille;

Masseran Gestion-CGE). With the development of several new compounds, Nanobiotix's objective is to increase its leading position in the nanomedicine field.

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