



## Nanobiotix receives approval from ANSM to start new Clinical Trial with Lead Product NBTXR3

### *Second indication for NanoXray product in Head and Neck cancer patients*

**Paris, France, June 13, 2013 – NANOBIOTIX (Euronext: NANO)**, a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces today that its lead compound NBTXR3 has received authorization from the French Medicine Agency, ANSM<sup>1</sup>, to start a clinical trial in patients with locally advanced cancers of the oral cavity or oropharynx (head and neck cancer), at the Institut Curie, Paris, France, a French leading cancer treatment center. This represents a second indication for NBTXR3 which is also in clinical trials for soft tissue sarcoma.

The phase I trial will be an open-label non-randomized, dose escalation study of safety and tolerability evaluation of NBTXR3. The product will be implanted by intra-arterial (IA) or intra-tumor (IT) injection, and activated by high precision radiation therapy (Intensity-modulated radiation therapy - IMRT) delivered as per current medical practice. Patients with locally advanced squamous cell carcinoma of the oral cavity or oropharynx constitute the targeted population which includes frail and elderly patients. Two different administration schedules of NBTXR3 will be investigated simultaneously in 2 different groups of patients. Allocation of patients to the intra-tumor injection or intra-arterial injection depends on the patient and tumor singularity. Based on the observed safety, the recommended doses for further evaluation of NBTXR3 as intra-arterial or intra-tumor injection with radiotherapy will be selected.

The secondary objectives of the study include assessment of the tumor Response Rate and complete Response Rate by MRI, and the evaluation of local and general Progression Free Survival of NBTXR3. Furthermore, the feasibility of local administration, either intra-tumor or intra-arterial injection of NBTXR3, then activated by radiotherapy will be evaluated.

Approximately, 24 patients are expected to be treated in any schedule (IT or IA) of the trial, with a total of maximum 48 patients.

*“The approval from ANSM to start a second clinical trial with NBTXR3 in Head and Neck cancer patients is a major milestone for Nanobiotix,”* said Laurent Levy, PhD, CEO of Nanobiotix. *“This follows the recent positive intermediate results from the clinical study of NBTXR3 in advanced Soft Tissue Sarcoma patients, which continues the regulatory pathway to market.”*

Head and neck cancer represents a group of biologically similar cancers that appear in the mouth, the nose, the sinuses and at the top of the aerodigestive tract. This type of cancer can be

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<sup>1</sup> Agence Nationale de Sécurité du Médicament et des produits de santé

cured if detected early. With large tumours in this area, the most common method of treatment is some form of surgery or radiation therapy. The issue with surgery is its detrimental effect on the patient's function, in terms of swallowing, breathing or speech - and cosmetic appearance.

The aim of using the NanoXray product, NBTXR3 in radiation therapy is to improve tumor destruction and maintain the patients' function and appearance.

*“Head and neck cancers are a major concern of public health in some European countries and across Asia. There is an immediate need for innovative therapies in this type of cancer. NBTXR3 may significantly help to improve the quality of life in this patient population including frail and elderly patients,”* said Alain Herrera, oncologist and non-executive board member of Nanobiotix.

Nanobiotix's therapeutic aim is to help patients in the fight against cancer and enhancing the effect of radiotherapy treatment. Nanobiotix is committed to bringing science to healthcare and to improve patients' quality of life.

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#### **About NANOBIOTIX**

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a 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 to provide a new, more efficient treatment for cancer patients. NanoXray products are compatible with current radiotherapy treatments and are meant to treat a wide variety of cancers via multiple routes of administration. Nanobiotix's lead product NBTXR3, based on NanoXray, is currently under clinical development for soft tissue sarcoma. The Company has partnered with PharmaEngine for clinical development and commercialization of NBTXR3 in Asia. The Company is based in Paris, France.

For more information, please visit [www.nanobiotix.com](http://www.nanobiotix.com)

#### **About NANOXRAY**

Nanobiotix's first-in-class, proprietary technology called NanoXray is at the forefront of a new era of nanomedicine, where nanoparticles are not just a vehicle for targeted drug delivery, but have become the principal active element. The NanoXray technology is based on the physical properties of hafnium-oxide nanoparticles and is used to enhance the efficacy of radiotherapy treatment for a variety of cancer indications.

Nanoparticles are designed to enter tumor cells and, upon activation by a standard dose of radiation, they emit large amounts of electrons resulting in the generation of free radicals that destroy cancer cells (the same mode of action than radiotherapy but largely amplified). Nanoparticle-enhanced radiotherapy therefore amplifies the lethal dose of energy locally within the tumor without changing the effect of the dose passing through surrounding healthy tissues.

By changing the coating of the nanoparticles, Nanobiotix is developing three different products that can be administered either by direct injection into the tumor (NBTXR3), intravenous injection (NBTX-IV) or topical application to fill tumor cavities after surgery (NBTX-TOPO). The product applied will depend on type of tumor and the patient's specific clinical needs. NanoXray products are classified as a medical device in Europe and as a drug in the US. They are compatible with current radiotherapy methods with respect to equipment and protocols, as well as with older radiotherapy equipment or any radiation based therapy (brachytherapy, proton therapy...).

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