



*Small but heading for a big time*

## **Nanobiotix strengthens its NanoXray pipeline with the launch of NBTX-TOPO development, the first nanotherapeutic with embedded radar**

### **1 product, 2 skills**

**Paris, France, 6 December, 2013 – NANOBIOTIX (Euronext: NANO)**, a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces today, in accordance with its plans, the selection of its new product, NBTX-TOPO, in view of its preclinical development.

Third product from the NanoXray platform, this unique product combines two important functions: a more efficient eradication of remaining cancer cells following the surgical removal of a tumor and a more accurate localization of a tumor. NBTX-TOPO is potentially applicable for all types of post-operative radiotherapy.

This is the third product from the NanoXray technology platform to be developed which is a major milestone achievement.

#### *Technology:*

The NBTX-TOPO product is a gel containing nanoparticles which is designed for direct application to the "tumor bed", the cavity left following the surgical removal of a tumor. This product could form part of the standard procedure to prepare a site for post-operative radiotherapy to destroy residual cancer cells.

**This unique product could present for the first time a combined solution addressing two unmet medical needs of post-operative radiotherapy:**

1. Enhance the elimination of residual cancer cells in the "tumor bed"

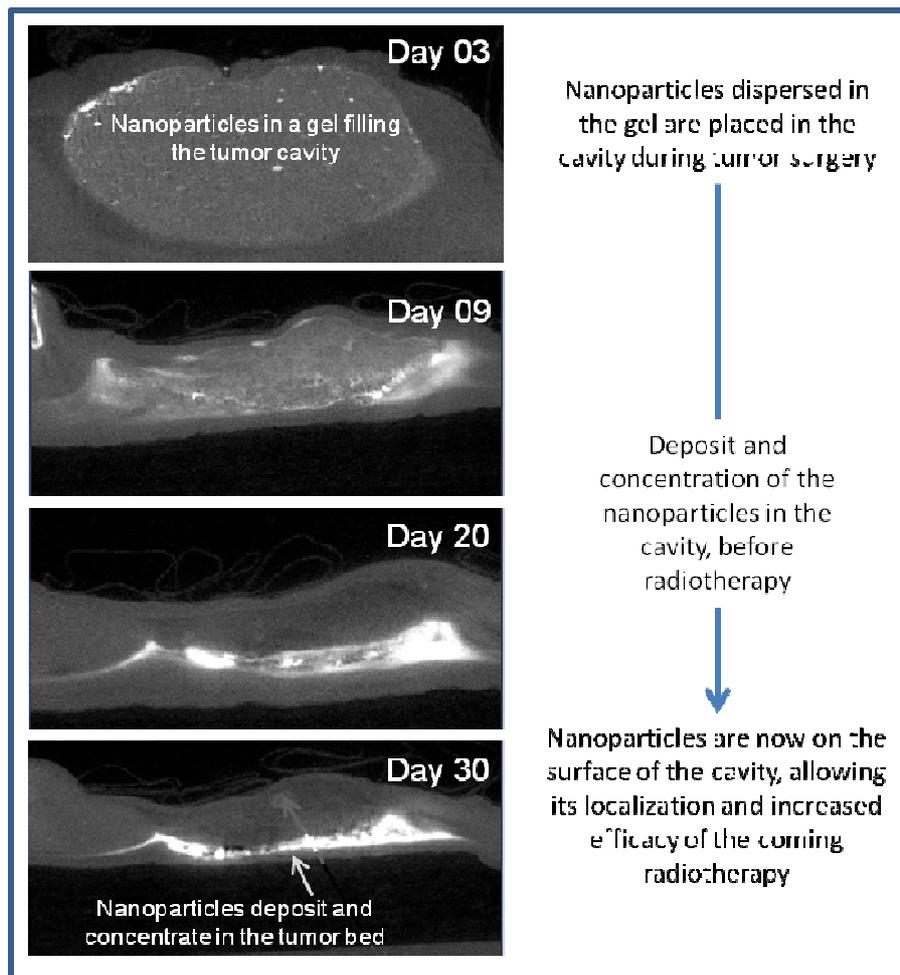
NBTX-TOPO originates from the NanoXray pipeline and therefore its properties are based on the physical mode of action of hafnium nanoparticles. Under the action of radiation therapy, the nanoparticles maximize X-ray absorption within cancer cells, without increasing the dose received by surrounding healthy tissues.

As a therapeutic product for use post-operatively, NBTX-TOPO could potentially better target and destroy remaining cancer cells, i.e. not removed during tumor resection. The goal is to prevent local or distant recurrence caused by any remaining cells.

2. Assist in the localization of the "tumor bed" post surgery, i.e. map the exact site where the tumor was removed to better position the radiation dose for subsequent treatment

In addition to a therapeutic effect, NBTX-TOPO enables the better visualization of the tumor bed because the hafnium crystals inside each nanoparticle are radio-opaque to X-rays. The radiation oncologist can thus better assess the positioning of the "tumor bed" thereby helping with greater targeting accuracy for delivering X-rays exactly to the site of interest.

The therapeutic action of NBTX-TOPO is therefore enriched with a support tool for the practice of post-operative radiotherapy, thereby increasing the intrinsic value of the product to the radiation oncologist.



***Illustration of the operational principle of NBTX-TOPO in an animal model***

***Product indications:***

The applications of NBTX-TOPO could be to all types of post-operative oncology radiation therapy, including breast cancers, lung cancers, vertebral metastasis or soft tissue sarcomas.

***Market potential:***

The market potential of the first indications could make NBTX-TOPO the second most important product for Nanobiotix after NBTXR3.

<b>NBTX-TOPO</b>		
<b>Indication</b>	<b>Incidence</b>	<b>Target population</b>
Breast cancer	517 970	<b>531 800</b>
NSCLC	954 536	
Bone metastasis	225 172	
Retroperitoneum STS <sup>1</sup>	3 276	
<b>Total</b>	<b>1 700 954</b>	
Unless indicated patients numbers of EU5 (France, Germany, Italy, Spain, United Kingdom), US and Japan		
<sup>1</sup> Data for EU and US only		

(Source: DATAMONITOR and GLOBAL DATA)

### ***NBTX-TOPO: targeted indications and population size***

#### *Development program:*

Moreover, NBTX-TOPO has benefited from experience and technological approaches already used for another NanoXray product, NBTXR3, which is already in clinical trials and tested in two first indications. From a regulatory point of view, this represents an advantage in terms of non-clinical development and cost as preclinical trials of NBTXR3, first product of the company, provide a solid base of toxicological program.

NBTX-TOPO benefiting from these advantages, the Company could envisage the completion of the related regulatory preclinical trials by the end of 2014. The Company does not intend, however, to divert from its main goal, i.e., the clinical development of its most advanced product, NBTXR3.

**Laurent Levy, CEO of Nanobiotix, comments:** « *The launch of the NBTX-TOPO development is consistent with the plans we have announced and is part of our strategy for the NanoXray pipeline development. We aim to offer innovative nanomedicine therapeutic tools to facilitate the work of physicians. With NBTX-TOPO, this represents the first time a product could potentially improve the effectiveness of post-operative radiotherapy, with better localization and elimination of residual cells – a significant aid to helping patients fight cancer.* »



#### **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 products that can be administered either by direct injection into the tumor or intra-arterial injection (NBTXR3), topical application to fill tumor cavities after surgery (NBTXR3 TOPO) or by general intravenous injection (NBTX-IV). 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.

First targeted indications are: primary liver cancer, multiform glioblastoma, rectal cancer, prostate cancer, head and neck cancers, advanced stage tumors that have invaded surrounding lymph nodes, lung carcinoma; breast cancer and retroperitoneal soft tissue sarcomas.

**About NANOBIOTIX - [www.nanobiotix.com](http://www.nanobiotix.com)**

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 and locally advanced head and neck cancer. The Company, based in Paris, France, has partnered with PharmaEngine for clinical development and commercialization of NBTXR3 in Asia.

Nanobiotix is listed on the regulated market of NYSE Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP).

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