Small but heading for the big time

FDA approved Investigational New Drug for NBTXR3 in a new clinical study in prostate cancer

Paris France, Cambridge MA, USA, January 4th, 2016 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces the US Food and Drug Administration (FDA) has approved the Company's Investigational New Drug (IND) application on the 30th of December. This allows Nanobiotix to launch its first clinical study in the US for its lead product NBTXR3 in prostate cancer, a new and very significant indication.

The FDA approval enables the Company to initiate a phase I/II prospective, open-label, two cohorts and non-randomized trial, in the large prostate cancer patient population. The first part of the trial should involve departments of radiation oncology of from three reference US oncology centers.

Nanobiotix is seeking to develop NBTXR3 for patients with intermediate and high-risk prostate cancer, with the aim of providing effective tumor destruction and disease control. Prostate cancer is the second most common form of cancer in the US among the male population: one out of seven men will be diagnosed with prostate cancer, and it is the second leading cause of cancer death (*American Cancer Society*).

Efficient local control is key for treatment of the primary prostate tumor to prevent relapse and subsequent spreading of the disease (metastasis). Radiotherapy is used for that purpose, but presents limitations in such patient population. The importance of the delivered energy dose in improving disease outcome has been extensively demonstrated. More precisely literature data have shown that increasing the radiotherapy energy dose significantly improve the local control and decrease the distant failure.

NBTXR3 is a nano-sized radio-enhancer that operates at the tumor level, bound and captured by cancer cells. Using NBTXR3 in combination with radiotherapy may significantly open the therapeutic window and improve efficacy by increasing the energy dose deposit within the malignant tissues, without adding toxicity to surrounding healthy tissues.

Laurent Levy, Nanobiotix CEO commented: "*The FDA approval opens the regulatory pathway for our lead product NBTXR3 in the US, the largest market for cancer therapeutics. Expansion in new indications and global development of NBTXR3 are key to establish this technology as a new standard of care".*

In addition to the prostate cancer trial, Nanobiotix is currently running trials in five indications across Europe and the Asia-Pacific Region: a registration trial in soft tissue sarcoma and Phase I/II trials in liver cancers (HCC and liver metastases), head and neck cancers and rectal cancer (in Asia by Nanobiotix's partner PharmaEngine).

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Prostate Cancer trial – Study Design

The design of this clinical research is based on the determination of the prostate cancer risk and two modalities of radiation therapy. The study will treat patients with several risk factors of their disease. These factors define intermediate and high-risk prostate cancer, where characterization of the tumor molecular features lead to an improved classification of the disease risk. Many patients who die of prostate cancer initially present with tumors confined to the gland that represent true high-risk disease for which new therapies are needed.

Furthermore, the study includes two different types of radiation therapy (or two different modalities for NBTXR3 activation). It tests NBTXR3 with external beam radiation therapy delivered as intensity modulated radiotherapy and other group of patients using the association of brachytherapy and external beam radiation therapy. Both radiation treatments represent modern approaches used in clinical centers of reference.

About NANOBIOTIX: www.nanobiotix.com

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 s 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, rectal cancer (PharmaEngine) and liver cancers (HCC and metastatic). 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.

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