



*Small but heading for the big time*

## PharmaEngine will join Nanobiotix' pivotal trial for NBTXR3 in Soft Tissue Sarcoma to accelerate its development in Asia-Pacific

*PharmaEngine to make milestone payment to Nanobiotix in October 2014 to recognize the value created*

Paris, France, 8 October, 2014 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205– PEA PME eligible), a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer today announces the update of the development plan for NBTXR3. Nanobiotix and its partner PharmaEngine Inc., a biopharmaceutical company focusing on the development of in-licensed oncology drugs, reinforce their collaboration to obtain faster market authorization for NBTXR3 in the Asia-Pacific region.

Laurent Levy, CEO of Nanobiotix said: *“As planned, we should start the pivotal phase before the end of the year, the association of PharmaEngine to the trial is an excellent news. This reinforced collaboration will allow us to pool resources and data leading to a more impactful study for this first key indication. Moreover PharmaEngine’s direct collaboration to the last phase of development of NBTXR3 is a new plan that should allow a faster access to the Asian market.”*

### **Soft Tissue Sarcoma**

Following the very positive pilot Phase I results for advanced **soft tissue sarcoma (STS)** recently presented at the American Society of Clinical Oncology (ASCO) annual meeting, PharmaEngine and Nanobiotix have decided to accelerate the clinical development of NBTXR3 in the Asia-Pacific region.

The planned European pivotal trial for NBTXR3 in soft tissue sarcoma will be broadened to Asia-Pacific where PharmaEngine will open additional clinical centers in multiple countries. Nanobiotix is sponsoring the global trial and PharmaEngine is co-sponsoring for the Asia-Pacific territory. The partners will bear the costs of the trial in their respective territories.

The expanded soft tissue sarcoma trial will provide additional clinical centers in multiple countries in Asia-Pacific, a larger cohort of enrolled patients and a more efficient study as Nanobiotix and PharmaEngine will share patient data. This may lead to faster market approval in the Asia-Pacific region than originally anticipated. An ongoing pivotal trial in the Asia-Pacific region could also facilitate the pathway for other indications in this region due to the available clinical data from patients in soft tissue sarcoma.

Nanobiotix plans to begin this pivotal trial and the patient recruitment before the end of 2014. Market authorization in Europe is expected in 2016.

### **Other NBTXR3 indications**

PharmaEngine is progressing its development in the rectal cancer indication in Taiwan and is in discussions with the Taiwanese regulatory agency. NBTXR3 could also be developed in other indications as the potential is broad especially for head and neck cancer, esophagus cancer, glioblastoma, cervix cancer, etc.

In addition, Nanobiotix and PharmaEngine are conducting pre-clinical studies in parallel to enable the two companies to start clinical studies in primary liver cancer in their respective territories. Liver cancer is a major health problem in Asia that causes one of the greatest number of deaths each year worldwide (695,000 deaths per annum). Moreover, countries like Taiwan, Japan, Korea, and China have a large prevalence of this disease.

### **Financials**

The accelerated development in Asia-Pacific will trigger a milestone payment of US\$1 million linked to the development stage of NBTXR3. Nanobiotix will receive such amount from PharmaEngine in October 2014. In accordance with the agreement between Nanobiotix and PharmaEngine, Nanobiotix is eligible for further development and commercialization milestone payments. All these payments may amount to a total of US\$56 million plus tiered, up to double-digit royalties on all net product sales in the Asian-Pacific region.

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### **About NBTXR3 in Soft Tissue Sarcoma (STS)**

STS are cancers arising from different types of tissues such as fat cells, muscles, joint structures, small vessels, etc. In resectable cases, surgery is the only potentially curative treatment and constitutes the basis to achieve prolonged survival.

Nevertheless, a considerable proportion of patients have locally advanced primary or relapsed tumors that cannot be removed with clean margins. Patients with big tumors are threatened with amputation for complete tumor removal. Progress of surgical techniques and the use of pre-operative radiotherapy have improved the disease outcome. However local and distant failures are frequently observed.

There is strong evidence (scientific literature) that supports the importance of local control of tumor in patients with locally advanced STS. Indeed, achieving local control in these patients presenting with locally advanced disease is a determinant factor to improve disease free and overall survival. This is not surprising considering similar outcomes have been observed for other cancers.

Patients with high risk STS have few therapeutic options. Innovative treatments aimed at optimizing cancer cell killing and surgical feasibility are needed.

Treatment with NBTXR3 nanoparticles and radiotherapy in locally advanced STS aims to destroy tumors more efficiently, to facilitate surgery and enable complete malignant tissue extraction during surgery.

NBTXR3 is a selective radioenhancer. The injected nanoparticles penetrate tumor cells and when exposed to radiotherapy make feasible the deposition of a high energy dose within the cancer cell, increasing cell killing with the intent of improving resectability and disease outcome.

### **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 (Soft Tissue Sarcoma, Breast Cancer, Liver Cancer, H&N cancer, Glioblastoma, Prostate...) 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 Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP).



**About PharmaEngine, Inc. (TWO: 4162)** - <http://www.pharmaengine.com>

PharmaEngine, Inc. is a biopharmaceutical company established in Taipei, Taiwan. PharmaEngine focuses on the development of new drugs for the treatment of cancer and Asian prevalent diseases. In addition to the NBTXR3 project, PharmaEngine has two other projects: PEP02 (aka MM-398), a nanoliposomal irinotecan for the treatment of metastatic pancreatic cancer, is at the pre-NDA stage; and PEP06, which is at the drug discovery stage.

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