# Nanobiotix reports positive Phase I/II preliminary data on feasibility and safety of NBTXR3 in liver cancers trial

**Good safety and feasibility of the treatment at 10% dose level**

**Third indication in global development confirming transferability across different cancers**

**Paris, France and Cambridge, Massachusetts, USA, December 14, 2016 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205)**, a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, today announces a positive readout of initial data on the safety and feasibility from the first patients treated in its Phase I/II trial evaluating NBTXR3 in liver cancers, including primary (Hepatocellular, HCC) and metastatic tumors.

Patients with either HCC or liver metastases frequently cannot undergo surgery and have very few or no therapeutic options available. Radiation therapy has been shown to improve outcomes of these patients. Clinical trials have shown a direct correlation between higher doses of radiation therapy and increased survival, in both patient populations. The delivery of a high radiation dose is complex and cannot be done in an optimal way in most situations due to toxicity. NBTXR3 aims to amplify the energy dose within the tumor to offer better clinical results and more therapeutic options to improve the poor prognosis of these populations.

Nanobiotix's Phase I/II trial evaluates the safety and preliminary efficacy of NBTXR3 nanoparticles administrated by intra-tumoral (IT) or intra-arterial (IA) injection and activated by high precision radiation therapy, delivered as high dose fractions (Stereotactic Body Radiation Therapy (SBRT)) for the treatment of liver cancers.

Elsa Borghi, CMO of Nanobiotix: *"At this stage, the safety and feasibility data of NBTXR3 in liver cancers are excellent. Observations are similar to the results of our more advanced trials: Soft Tissue Sarcoma and Head and Neck cancers. This is significant because these trials cover very different patient and disease profiles. Based on the information gathered to date, we anticipate that by the end of this phase, we will have identified the appropriate conditions to use NBTXR3 in these patients populations. Once again, all transferability data show the potential of broad applicability of NBTXR3 for use with radiotherapy in the treatment of solid tumors*."

**Preliminary data results:**

1. **Good safety profile with no serious adverse events recorded**

Two sub-groups of patients have been treated at 10% dose of NBTXR3, with Intra Tumoral injections (IT), using either 24 Gy or 45 Gy total radiation dose, based on patients dosimetric constrains.

Intra-arterial injection has not been explored so far because the Intra Tumoral (IT) injection has been shown to be feasible and successful.

Good safety has been demonstrated within these patients as well. To date, all treated patients have completed their radiation therapy course, confirming good local tolerability and no changes in liver hepatic functions (MELD Score evaluation).

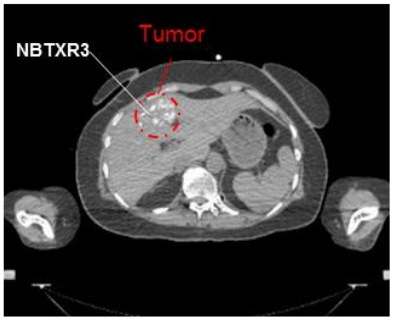
2. **Treatment feasibility and appropriate distribution demonstrated**

The data validate the feasibility of the injection with a volume level equivalent to 10% of the baseline tumor volume in both patient populations: primary cancer (HCC) and liver metastasis.

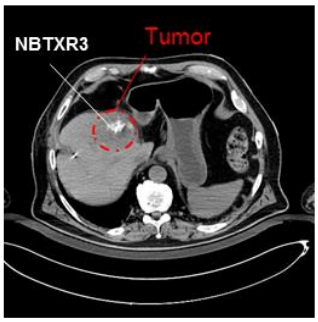
The product appears to stay within the tumors with no leakage in the surrounding healthy tissues from the day of injection until end of radiotherapy treatment (illustration 1 & 2). It confirms and supports the findings reported from the clinical trials in Soft Tissue Sarcoma or Head and Neck cancers patients.

## Illustration 1: product distribution post injection

Liver metastases patient
CT scan: Post injection



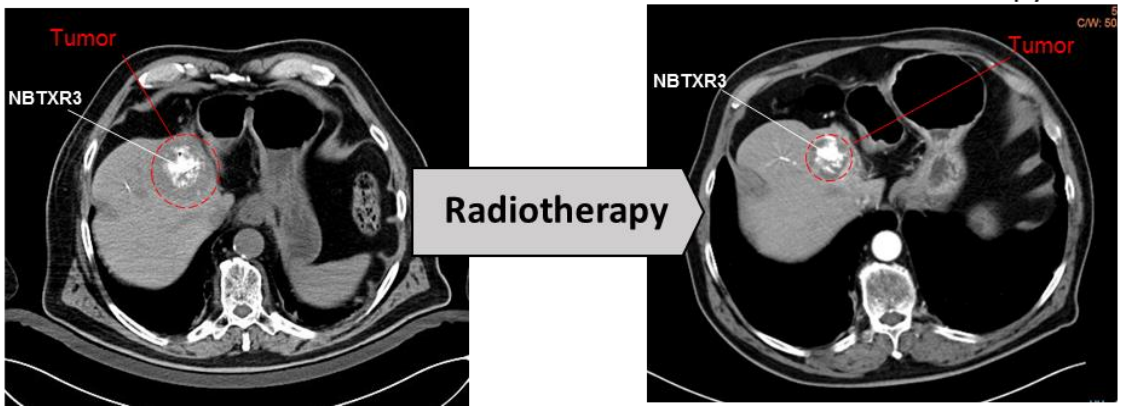

Hepatocellular cancer patient
CT scan: Post injection




## Illustration 2: product distribution post injection and post radiotherapy

CT scan: Post Injection

CT Scan: Post Radiotherapy




### 3. 10% volume level secured, further levels under evaluation

The 10% dose level was successfully evaluated in HCC and metastatic patients. The 10% dose level is the recommended NBTXR3 volume for the treatment of soft tissue sarcoma (STS) in the act.in.sarc study (www.actinsarc.com), the most advanced indication developed by Nanobiotix (Phase II/III).

The trial is now recruiting next dose levels to evaluate safety and feasibility at higher doses along with exploratory efficacy endpoints (complete Response Rate, Progression Free Survival and Overall Survival).

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### About liver cancers

According to WHO, liver cancers are the second most common cause of cancer death in the world with 745,000 deaths each year, and 800,000 new liver cancer patients per year.

Liver cancers are challenging diseases to address. Stereotactic Body Radiation Therapy (SBRT) is the safest and most modern radiotherapy currently available for the treatment of malignant liver tumors but SBRT has been shown to be efficient only in specific subsets of population with small tumors. Complete response is a rare event and local control is often compromised in big tumors, metastases and HCC with portal vein tumor thrombosis and short progression Free Survival and Overall survival.

### About NBTXR3 trial protocol in liver cancer

NBTXR3 is a first-in-class radio-enhancer nanoparticle designed for direct injection into malignant tumors. NBTXR3 has the potential to improve radiotherapy efficacy by destroying locally advanced cancers more efficiently. It has been engineered to

increase the local absorption of the radiotherapy dose and thereby increasing the efficacy of radiotherapy without increasing toxicity or causing damage to surrounding healthy tissues.

The first phase of the ongoing, multicenter open-label, single-arm study is a dose-escalation to evaluate the safety, feasibility and preliminary clinical activity along with determining the right dose of NBTXR3 in this indication. The second phase of the trial will be a dose-expansion phase, which will be a cohort expansion at the recommended dose of NBTXR3.

Patients receive a single injection administration of NBTXR3 24 hours before the beginning of the radiotherapy treatment. The total maximum radiotherapy dose is 45 Gy, delivered as three fractions of 15 Gy each, over 5 to 7 days.

## 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 including soft tissue sarcoma, head and neck cancers, liver cancers, prostate cancer, breast cancer, glioblastoma, etc., via multiple routes of administration.

NBTXR3 is being evaluated in: soft tissue sarcoma (STS), head and neck cancers, prostate cancer, and liver cancers (primary and metastases). Additionally, head and neck cancer and rectal cancer trials led by Nanobiotix's Taiwanese partner, PharmaEngine, are underway in the Asia Pacific region. The Company has filed in August 2016 for market approval (CE Marking) in Europe for its lead product NBTXR3.

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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