Small but heading for the big time

Nanobiotix presents successful Phase I results for its lead nanomedicine product NBTXR3 at ASCO

Final results demonstrate a very good safety, treatment feasibility and promising signs of efficacy in patients with advanced Soft Tissue Sarcomas

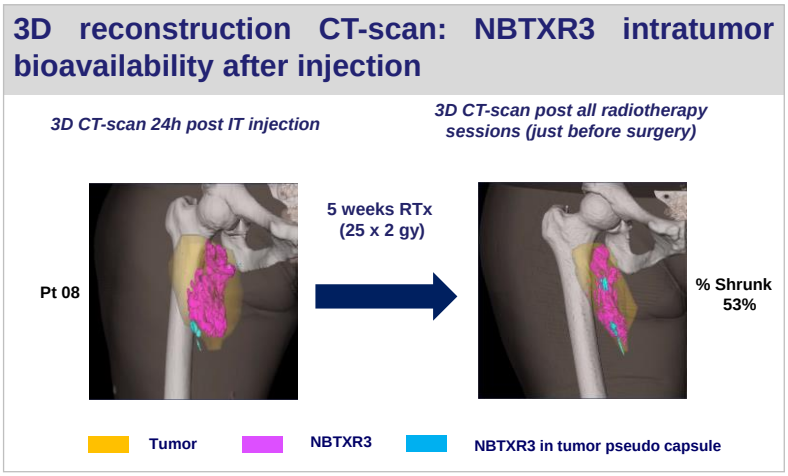
Paris, France, 2 June, 2014 – **NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205)**, a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announced the successful completion of the first in human study of its lead NanoXray product, NBTXR3, which will be presented today at the American Society of Clinical Oncology (ASCO) annual meeting.

The Phase I clinical study established that intratumoral injection of NBTXR3 followed by radiotherapy has a good safety profile in patients with locally advanced soft tissue sarcoma (STS), who have an important risk of relapse and few treatment options.

These results allow Nanobiotix to proceed to the pivotal phase, which is the final step leading to registration (CE mark).

The study showed that promising signs of antitumor activity for different sarcoma subtypes were observed. Interestingly, tumor shrinkage and pathological response were observed in well-known refractory tumors. All patients underwent a wide surgical resection. This optimal surgery impacts the local recurrence rate, improving patient prognosis since local disease control prolongs progression free survival and overall survival in high grade sarcomas.

Elsa Borghi, CMO of Nanobiotix said: "*These results are really encouraging, the feasibility of injecting different sarcoma subtypes with varying volumes of NBTXR3 nanoparticles was tested in this phase I study and a very good tolerance was observed. We are pleased to announce that each patient has been successfully operated on. This has reinforced the fact that radiotherapy with NBTXR3 has the potential to be an effective pre-operative treatment and offer meaningful clinical benefit to patients with advanced Soft Tissue Sarcoma (STS). Now, further development of NBTXR3 is warranted and a pivotal trial is planned to start in Q4 2014.*"



The study enrolled 20 patients who received a single intratumoral injection of NBTXR3, at escalating volumes, followed by standard radiotherapy (50Gy RTx), as indicated in this clinical setting.

Primary endpoints included feasibility of the intratumoral implantation and safety. Secondary endpoints focused on the efficacy such as pathological response and RECIST (Response Evaluation Criteria In Solid Tumors) response, including tumor volume evaluation. Moreover, IntraTumoral permanence of NBTXR3 and operability were assessed.

Key findings:

- **Feasibility of the NBTXR3 injection** within the tumor mass across different tumor types and volumes (from 55.06ml to 3682.56ml) was demonstrated.
- **No leakage of NBTXR3 to the surrounding healthy tissues** was confirmed.
- Persistence of NBTXR3 during all sessions of radiotherapy: **optimal bioavailability over time**.
- Appropriate dispersion of the product within the tumor: diffusion in 3 dimensions.
- **Very good tolerance and local safety** of the product at volume 2.5%, 5%, 10% and 20% was observed.
- **Promising signs of antitumor activity** were observed in different sarcoma subtypes, such as undifferentiated sarcoma, rhabdomyosarcoma, and synovial sarcoma.
- **The recommended volume for the pivotal study is 10%**.

Laurent Levy, CEO of Nanobiotix commented: *"The completion of this Phase I study is a very important milestone for Nanobiotix. The next step for us is to initiate a pivotal study for NBTXR3 in patients with advanced soft tissue sarcomas. We expect to start enrolling patients by the end of 2014. This successful feasibility of our NBTXR3 approach in cancer patients also encourages us to expand the use of NBTXR3 in other indications like head and neck cancer, liver cancer, glioblastoma, rectal cancer and prostate cancer, and to think about developments of our other products, NBTX-IV and NBTX-TOPO."*

Detailed results

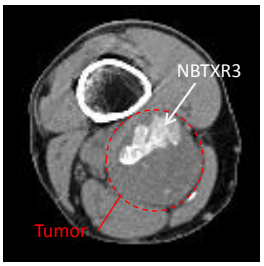
Feasibility of the intratumoral injection was confirmed.

The injection procedure was performed under local anesthesia and pre-medication with analgesic and sedative products. This first step of the clinical development demonstrated the feasibility of NBTXR3 intratumor injection at the 3 first volume levels, followed by radiotherapy.

Dispersion of NBTXR3 nanoparticles within the tumor

CT scan - 24h post IT injection- Day 2

Myxoid liposarcoma
Tumor volume: 1814.4 cc
NBTXR3 volume: 45 mL (2.5%)

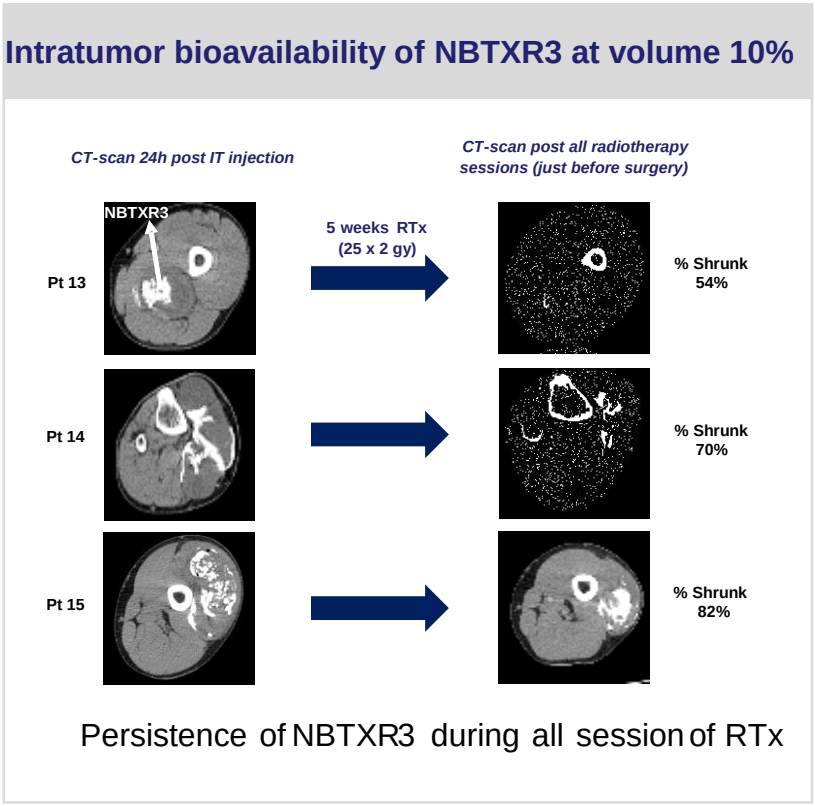


The treatment was safe

No early dose-limiting toxicity (DLT) was observed. Patients received the complete planed radiotherapy scheduled and dose. No grade 3-4 toxicity related to NBTXR3 occurred. Main grade 1-2 adverse events included injection pain/reaction, pyrexia, abdominal pain, pruritus and paresthesia.

Adequate bioavailability was demonstrated

Results confirmed that a single injection provides adequate bioavailability of NBTXR3 within the tumor over the five weeks of radiotherapy. No leakage of NBTXR3 to the healthy tissues was observed. Further, the evaluation demonstrated the permanence of NBTXR3 within the tumor, before surgery, i.e. 6 weeks after the end of the radiotherapy.

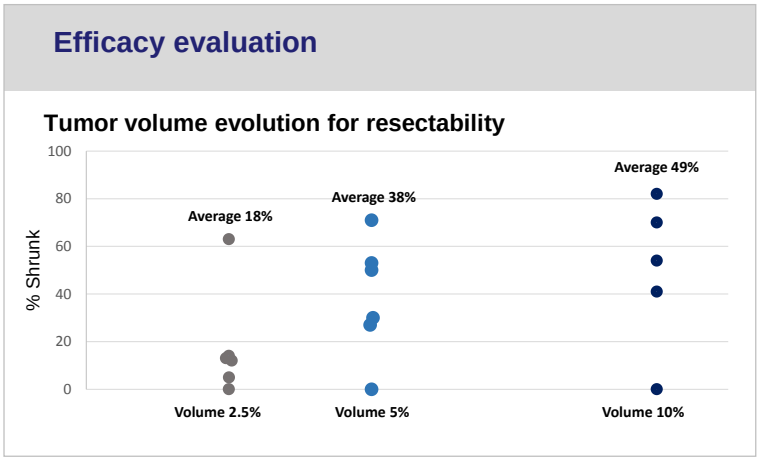


Promising signs of antitumor activity were observed in different sarcoma subtypes.

The basis of the management of the Soft Tissue Sarcoma patients is surgery. The wider the local excision, the lower the probability of cancer recurrence and amputation need. Currently and despite of pre-operative radiotherapy, surgery is still very challenging in the subset of patients with locally advanced soft tissue sarcoma of the extremity and trunk wall.

In this population, NBTXR3 activated by radiotherapy showed promising signs of antitumor activity in different sarcoma subtypes.

- 3/17 patients had pathological Response superior or equal to 90%.
- At 10% volume of NBTXR3, the average pathological Response was 74%
- Average tumor shrinkage increasing with NBTXR3 volume
    - Volume 2.5% , average of tumor volume shrunk was 18%
    - Volume 5%, average of tumor volume shrunk was 38%
    - Volume 10%, average of tumor volume shrunk was 49%
- All patients treated in the study had a wide surgical resection of the tumor



Notes to editors

About NBTXR3 in Soft Tissue Sarcoma (STS)

STS are cancers arising from different types of tissues such as fat cells, muscles, joint structures and 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 present with locally advanced primary or relapsed tumors and cannot be resected with clean margins. These 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 survival and overall survival. This is not surprising. Similar outcome is observed for other cancers.

Patients with high risk STS have few therapeutic options. Innovative treatments aimed at optimizing cancer cell killing and the 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 and thus improving resectability and disease outcome.

For more information:
https://clinicaltrials.gov/ct2/show/NCT01433068?term=NANOBIOTIX&rank=2

About NANOBIOTIX – 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 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 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).

For more information, please contact:

Nanobiotix	*Financial communication and investors relations*
Sarah Gaubert *Head of Communication and Public Affairs* +33 (0)1 40 26 07 55 contact@nanobiotix.com	*New***Cap** **Louis-Victor Delouvrier / Emmanuel Huynh** +33 (0)1 44 71 98 53 lvdelouvrier@newcap.fr

Media relations

France - *New***Cap**	Outside France - **Instinctif Partners**
Annie-Florence Loyer/ Nadège Le Lezec +33 (0)6 88 20 35 59 afloyer@newcap.fr / nlelezed@newcap.fr	**Melanie Toyne Sewell / Katherine Lynch** +44 (0) 207 457 2020 nanobiotix@instinctif.com

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