



## **NANOBIOTIX ANNOUNCES PUBLICATION OF PHASE III SOFT TISSUE SARCOMA DATA FOR FIRST-IN-CLASS NBTXR3 IN *THE LANCET ONCOLOGY***

- **Previously reported data from the registration study (Act.In.Sarc) in advanced Soft Tissue Sarcoma (STS) patients demonstrated a significant advantage in both pathological complete response (pCR) and rate of margin-negative resection (R0) for those treated with NBTXR3 activated by standard of care radiation therapy (RT) versus RT alone**
- **Data showed that an increase in efficacy was achieved with the addition of NBTXR3 without a significant difference in the safety profile compared to RT alone**
- **The trial validates the clinical application of the mode of action of this new class of treatment, which supports further investigation in a larger field of indications**

*“Act.In.Sarc results published in The Lancet Oncology show clear superiority of NBTXR3 activated by radiation therapy versus radiation alone as evidenced by the significant increase in complete response. As I have stated previously, NBTXR3 is an innovation that could bring real benefits to patients and change the standard of care. It is an honor to have this potential recognized by our scientific peers.”* – Pr. Sylvie Bonvalot, MD, PhD, Head of Sarcoma and Complex Tumor Surgery at the Curie Institute and Global Principal Investigator of the Act.In.Sarc Study.

*“The data published in The Lancet Oncology represent another important moment for our company, our partners, and our patients. As members of the global scientific community we have a responsibility to make positive and substantial contributions to our field. Achievement of first European market approval provided validation for our contribution from a regulatory perspective, but recognition from our peers is especially rewarding.”* – Edwina Baskin-Bey, MD, Chief Medical Officer of Nanobiotix.

**Paris, France and Cambridge, Massachusetts, USA, July 9, 2019** – [NANOBIOTIX](#) (Euronext: NANO – ISIN: FR0011341205), a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced that the previously reported results from the Phase II/III Act.In.Sarc trial evaluating NBTXR3 in patients with advanced STS have been [published online](#) in *The Lancet Oncology*.

The registration study met its primary (pCR) and secondary (R0 rate) endpoints. The increased proportion of patients with pCR among those given NBTXR3 as a single injection prior to standard of care RT when compared to RT alone (approximately twice as many), provides robust justification for the efficacy of nanoparticle-enhanced tumor cell death. The overall safety profile of NBTXR3 activated by RT was similar to RT alone, with manageable and reversible transient immune reactions observed in those treated with NBTXR3 and RT. More detail on the results can be found [here](#).

The data from the Act.In Sarc trial were the basis for first European market approval (CE marking) of NBTXR3 in advanced STS of the extremity and chest wall, under the brand name Hensify®. With STS results validating the efficacy and safety profile of the product, the company will continue its development strategy to evaluate NBTXR3 in multiple global (US, EU and APAC) clinical trials with a focus including but not limited to: head and neck, liver, lung and prostate cancer, as well as tumors that may benefit from NBTXR3 in combination with immune-oncology agents.

**-Ends-**

## About Phase II/III Act.In.Sarc Study

Nanobiotix and its partner, PharmaEngine treated 179 patients in 32 sites across 11 countries in Europe and Asia. The Global Principal Investigator is Pr. Sylvie Bonvalot, MD, PhD (Institut Curie, Paris, France).

### Primary Endpoint

**Pathological Complete Response Rate (pCR):** A pathological complete response is defined as the presence of less than 5% of residual malignant viable cells in the surgically removed tissue. The primary endpoint compared the proportion of patients with pCR between the two randomized arms. This was determined by an independent pathological central review according to Wardelmann et al., 2016.

### Key Secondary Endpoint

**Resection Margin Status:** The resection margin status is evaluating the quality of surgery. Surgery remains the mainstay of care for advanced soft tissue sarcoma. The primary surgical objective is the complete removal of the tumor with negative resection margins (R0). Several retrospective studies suggest that surgical margin status predicts the risk of local and distant recurrence. In particular, negative surgical margins are significantly correlated to increased patients' survival.

## About NBTXR3

NBTXR3 is a first-in-class product designed to destroy tumors through physical cell death when activated by radiotherapy.

NBTXR3 has a high degree of biocompatibility, requires one single administration before the first radiotherapy treatment session, and has the ability to fit into current worldwide standards of radiation care. The physical mode of action of NBTXR3 makes it applicable across solid tumors such as lung, prostate, liver, glioblastoma, and breast cancers.

NBTXR3 is actively being evaluated in head and neck cancer with locally advanced squamous cell carcinoma of the oral cavity or oropharynx in elderly and frail patients unable to receive chemotherapy or cetuximab with very limited therapeutic options. Promising results have been observed in the phase I/II trial regarding the local control of the tumors. In the United States, based on the discussions with the Food and Drug Administration that occurred in the first half of 2019, the Company plans to begin the clinical trial authorization process in the second half of 2019 and commence a phase II/III clinical trial in locally advanced head and neck cancers.

Nanobiotix is also running an Immuno-Oncology development program. In the United States, the Company received approval from the Food and Drug Administration to launch a clinical trial of NBTXR3 activated by radiotherapy in combination with antiPD-1 antibodies in lung, and head and neck cancer patients (head and neck squamous cell carcinoma and non-small cell lung cancer).

The other ongoing NBTXR3 trials are treating patients with liver cancers (hepatocellular carcinoma and liver metastasis), locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma.

Further, the company has a large-scale, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (9 new phase I/II clinical trials in the United States) to evaluate NBTXR3 across head and neck, pancreatic, thoracic, lung, gastrointestinal and genitourinary cancers.

## About NANBIOTIX: [www.nanobiotix.com](http://www.nanobiotix.com)

Incorporated in 2003, Nanobiotix is a leading, clinical-stage nanomedicine company pioneering new approaches to significantly change patient outcomes by bringing nanophysics to the heart of the cell.

The Nanobiotix philosophy is rooted in designing pioneering, physical-based approaches to bring highly effective and generalized solutions to address unmet medical needs and challenges.

Nanobiotix's first-in-class, proprietary lead technology, NBTXR3, aims to expand radiotherapy benefits for millions of cancer patients. Nanobiotix's Immuno-Oncology program has the potential to bring a new dimension to cancer immunotherapies.

Nanobiotix is listed on the regulated market of Euronext in Paris (Euronext: NANO / ISIN: FR0011341205; Bloomberg: NANO: FP). The Company's headquarters are in Paris, France, with a U.S. affiliate in Cambridge, MA, and European affiliates in Spain and Germany.

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## Disclaimer

*This press release contains certain forward-looking statements concerning Nanobiotix and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-018 on April 30, 2019 (a copy of which is available on [www.nanobiotix.com](http://www.nanobiotix.com)) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.*