



NANOBIOTIX ANNOUNCES FIRST EVER RADIOENHANCER TO RECEIVE EUROPEAN MARKET APPROVAL

- Hensify®(NBTXR3) received European market approval (CE mark) enabling commercialization in 27 European Union countries for the treatment of locally advanced soft tissue sarcoma
- Hensify®--a first-in-class radioenhancer--offers cancer patients an innovative treatment with a broadly applicable mechanism of action
- After positive phase II/III data, this approval represents significant step forward in establishing NBTXR3 as a major oncology treatment

Laurent Levy, CEO of Nanobiotix, commented, “We could not be more proud to receive market approval in Europe for Hensify®. This approval validates more than 15 years of hard work, cutting edge science, and a fierce commitment to changing the lives of patients. This is a significant achievement and represents just one more step in our mission to improve life for millions of people around the world.”

Paris, France, and Cambridge, Massachusetts (USA) April 4, 2019 – [NANOBIOTIX](#) (Euronext : NANO – ISIN : FR0011341205), a clinical-stage nanomedicine company pioneering new approaches in the treatment of cancer, announced today that Hensify® (NBTXR3) has obtained a CE mark for the treatment of locally-advanced soft tissue sarcoma (“STS”). Hensify® is the brand name for NBTXR3 as approved for the treatment of locally-advanced STS.

Hensify® is a first-in-class product introducing a new, physical mechanism of action. This innovative product was designed by Nanobiotix to physically destroy tumors and activate the immune system for both local control and systemic disease treatment when combined with radiation therapy. In addition to Hensify®, NBTXR3 is currently under evaluation in various other indications such as lung cancer, head and neck cancers, liver cancer, and prostate cancer.

Hensify® is an aqueous suspension of crystalline hafnium oxide (HfO₂) nanoparticles designed for injection directly into a tumor prior to a patient’s first standard radiotherapy treatment. When exposed to ionizing radiation, Hensify® amplifies the localized, intratumor killing effect of that radiation. The dose of X-ray delivered to the tumor is magnified, whilst the dose passing through healthy tissues remains unchanged. Hensify® requires a single administration and will fit into current worldwide standards of radiation care.

STSs are rare cancers that develop in different types of soft tissues including fat, muscles, joint structures and blood vessels. Radiotherapy followed by surgery is part of the typical treatment regimen for STS patients in Europe. The *Act.In.Sarc* phase II/III trial was a prospective, randomized (1:1), multinational, open label and active controlled two armed trial of 180 adult patients with locally advanced STS of the extremity or trunk wall. The objective of the trial was to evaluate the pre-operative efficacy and the safety of Hensify® activated by radiotherapy compared to the standard of care (radiotherapy alone).

The positive *Act.In.Sarc* study results were presented at the 2018 ASTRO and ESMO Annual Congresses. The trial achieved its primary endpoint with a pathological complete response (<5% viable cancer cells) rate of 16.1% in the Hensify® arm compared to 7.9% in the control arm (p=0.0448). In addition, in the subgroup of patients with a more aggressive disease (histologic grade 2 and 3), a pathological complete response was achieved in four times as many patients in the Hensify® arm as in the control arm (17.1% compared 3.9%).

Similar safety profiles were observed in the Hensify® arm and the radiation therapy alone control arm. Hensify® did not impair the patients’ ability to receive the planned dose of radiotherapy and the radiotherapy safety profile was similar in both arms, including the rate of postsurgical wound complications. Hensify® was associated with grade 3-4 acute immune reactions which were manageable and of short duration. Further, Hensify® showed a good local tolerance in the trial and did not have any impact on the severity or incidence of radiotherapy-related adverse events.

Post-approval trials are planned across Europe and discussions on next steps regarding potential further development are ongoing.

About Hensify® (NBTXR3)

NBTXR3 is a first-in-class product designed to destroy, when activated by radiotherapy:

- tumors through physical cell death
- metastasis due to immunogenic cell death leading to activation of the immune system.

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 anti-PD-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 NANOBIOTIX: 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 the development and commercialization of Hensify®. 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 filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number D.17-0470 on April 28, 2017 as well as in its 2017 annual financial report filed with the French Financial Markets Authority on March 29, 2018 (a copy of which is available on 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. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country.