

NANOBIOTIX

EXPANDING LIFE

Nanobiotix Announces Initiation of New Clinical Study Evaluating NBTXR3 in Lung Cancer

June 30, 2021

- **First patient administered radiotherapy in phase I study evaluating NBTXR3 as a single-agent activated by radiotherapy in patients with non-small cell lung cancer amenable to re-irradiation**

Paris, France ; Cambridge, Massachusetts (USA) ; June 30, 2021 – [NANOBIOTIX](#) (Euronext : NANO — NASDAQ: NBTX – the “ Company”), a late-clinical stage biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced the initiation of a new phase I study evaluating NBTXR3 activated by radiation therapy (RT) for patients with non-small cell lung cancer (NSCLC) amenable to re-irradiation. The phase I is among five collaborator-led studies that are active and recruiting at The University of Texas MD Anderson Cancer Center (MD Anderson), and the third to enroll its first patient.

“Our ongoing collaboration with MD Anderson remains a critical component of our strategy as we seek to develop NBTXR3 as a solid tumor-agnostic, therapeutic combination-agnostic agent with the potential to change the practice of radiotherapy and immunotherapy,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. *“These collaborator-led studies not only provide patients with significant unmet need the opportunity to benefit from MD Anderson’s physicians, but also provide additional capacity for Nanobiotix to expand development of NBTXR3 into indications where innovation is urgently needed while remaining focused internally on our priority pathways in head and neck cancer and immunotherapy.”*

A Phase I Study of Reirradiation with NBTXR3 for Inoperable Locoregional Recurrent Non-Small Cell Lung Cancer

This phase I study, led by Saumil Gandhi, Assistant Professor, Department of Radiation Oncology, Division of Radiation Oncology, MD Anderson, investigates the safety and optimal dose of NBTXR3 when activated by radiation therapy for the treatment of non-small cell lung cancer that cannot be treated by surgery (inoperable) and has come back (recurrent). The study has a two-cohort, open label design consisting of two parts: (i) RT safety lead-in cohort recruiting up to 10 patients and NBTXR3 activated by RT dose-finding cohort recruiting up to 12 patients; and (ii) expansion at the recommended phase II dose (RP2D) with toxicity monitoring recruiting 12 patients. The dose levels explored to be explored are 22% and 33% of baseline gross tumor volume. The planned enrollment period is up to three years.

The patient population includes adults (age ≥ 18 years) with medically inoperable NSCLC with overlap between recurrent disease in need of treatment and prior RT. Given the design of the study, patients in the first cohort in part one will receive RT and be monitored for safety before the second cohort is opened where patients will receive injections of NBTXR3.

Five Studies Now Active and Recruiting in Clinical Collaboration

In addition to the lung cancer study described above, two phase II studies, each evaluating NBTXR3 in combination with anti-PD-1 for patients with head and neck cancer (inoperable locoregional recurrent amenable to reirradiation and recurrent metastatic with limited PD-L1 expression or refractory); one phase I study evaluating NBTXR3 in combination with chemotherapy for patients with esophageal cancer; and one phase I study evaluating NBTXR3 as a single-agent activated by RT for patients with pancreatic cancer are active and enrolling. As previously announced, the first patient has been injected with NBTXR3 in each of the esophageal cancer and pancreatic cancer studies. The first NBTXR3 injections in the phase II head and neck cancer studies are expected in the second half of 2021. All studies in the collaboration are led by MD Anderson and milestones will be reported as they are made available by the institution.

Next Steps for Collaborator-led Expansion of NBTXR3 Development as a Potentially Solid Tumor-Agnostic and Therapeutic Combination-Agnostic Agent

The clinical collaboration between Nanobiotix and MD Anderson is a collaborator-led expansion of the NBTXR3 development pipeline across indications and therapeutic combinations. One additional study evaluating NBTXR3 in combination with anti-CTLA-4 and anti-PD-1/L1 plus RadScopal™ in advanced solid tumors with lung or liver metastasis is planned to launch in the second half of 2021. Further studies evaluating the potential of NBTXR3 to address unmet needs throughout the oncology landscape are in discussion as part of the collaboration agreement and updates will be provided as the planning process evolves.

About NANOBIOTIX

Nanobiotix is a late-stage clinical biotechnology company pioneering disruptive, physics-based therapeutic approaches to revolutionize treatment outcomes for millions of patients; supported by people committed to making a difference for humanity. The company’s philosophy is rooted in the concept of pushing past the boundaries of what is known to expand possibilities for human life.

Incorporated in 2003, Nanobiotix is headquartered in Paris, France. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, Germany and Switzerland.

Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 umbrella patents associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system. The company’s resources are primarily devoted to the development of its lead product candidate– NBTXR3 —which is the product of its proprietary oncology platform and has already achieved market authorization in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on [LinkedIn](#) and [Twitter](#).

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Nanobiotix

Communications Department

Brandon Owens

VP, Communications

+1 (617) 852-4835

contact@nanobiotix.com

Investor Relations Department

Kate McNeil

SVP, Investor Relations

+1 (609) 678-7388

investors@nanobiotix.com

Media Relations

France – Ulysse Communication

Pierre-Louis Germain

+ 33 (0) 6 64 79 97 51

plgermain@ulyссе-communication.com

US – Porter Novelli

Dan Childs

+1 (781) 888-5106

Dan.childs@porternovelli.com

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