Nanobiotix Announces Completion of Phase 1 Dose Escalation and NBTXR3 Recommended Phase 2 Dose for the Treatment of Inoperable, Recurrent Lung Cancer in Patients Amenable to Re-Irradiation

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- Established recommended Phase 2 dose of NBTXR3 for the treatment of patients with inoperable, recurrent non-small cell lung cancer (“NSCLC”) who have previously received definitive radiation therapy
- Confirmation of injection feasibility and favorable safety profile in completed Phase 1 dose escalation part of the study support potential for later stage development of NBTXR3 for the treatment of patients with inoperable, recurrent NSCLC who are amenable to re-irradiation
- The dose expansion part of the Phase 1 study designed to further assess safety and evaluate early signals of efficacy is ongoing

PARIS and CAMBRIDGE, Mass., April 02, 2024 (GLOBE NEWSWIRE) -- 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 completion of the dose escalation part of a Phase 1 study evaluating potential first-in-class radioenhancer NBTXR3 for patients with non-small cell lung cancer (“NSCLC”) that cannot be treated by surgery (“inoperable”), and has come back (“recurrent”), whom have previously been treated with definitive radiation therapy and are amenable to re-irradiation. The Phase 1 study (“Study 2020-0123”) is being conducted by The University of Texas MD Anderson Cancer Center (“MD Anderson”) as part of an ongoing strategic collaboration with Nanobiotix.

“NBTXR3 is designed as a product candidate with the potential to improve treatment outcomes for patients with cancer in any setting where radiotherapy is a part of the treatment regimen. While these patients experience different cancer types and are each faced with unique challenges, what they share is an urgent need for therapeutic innovation with the chance to make a difference,” said Louis Kayitalire, MD, Chief Medical Officer at Nanobiotix. *“We believe the injection feasibility and favorable safety profile we have observed from the completed dose escalation part of this Phase 1 lung cancer study could pave the way for additional clinical development of NBTXR3 for patients with inoperable, recurrent lung cancer and patients amenable to re-irradiation.”*

The completed dose escalation part of Study 2020-0123 established the recommended Phase 2 dose after determination of injection feasibility and observation of a favorable safety profile. The expansion part of the study, further evaluating safety and early signals of efficacy, is ongoing.

About MD ANDERSON STUDY 2020-0123
MD Anderson Study 2020-0123 (NCT04505267) is a Phase 1 study evaluating the best dose and observing the adverse effects of NBTXR3 activated by radiation therapy (“RT”) for the treatment of non-small cell lung cancer (“NSCLC”) that cannot be treated with surgery (“inoperable”), and has come back (“recurrent”), in patients who have previously been treated with definitive RT. The primary objectives of the study include a safety assessment of re-irradiation in these patients and determination of the recommended Phase 2 dose of NBTXR3 activated by RT. The re-irradiation safety assessment part and the dose-finding part of the study have completed. An expansion part evaluating additional signals of safety, feasibility, anti-tumor response, and time-to-event outcomes is ongoing.

About NBTXR3
NBTXR3 is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles that is administered via one-time intratumoral injection and activated by radiotherapy. Its proof-of-concept was achieved in soft tissue sarcomas for which the product received a European CE mark in 2019. The product candidate’s physical mechanism of action (MoA) is designed to induce significant tumor cell death in the injected tumor when activated by radiotherapy, subsequently triggering adaptive immune response and long-term anti-cancer memory. Given the physical MoA, Nanobiotix believes that NBTXR3 could be scalable across any solid tumor that can be treated with radiotherapy and across any therapeutic combination, particularly immune checkpoint inhibitors.

Radiotherapy-activated NBTXR3 is being evaluated across multiple solid tumor indications as a single agent or in combination with anti-PD-1 immune checkpoint inhibitors, including in NANORAY-312—a global, randomized phase III study in locally advanced head and neck squamous cell cancers. In February 2020, the United States Food and Drug Administration granted regulatory Fast Track designation for the investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced HNSCC who are not eligible for platinum-based chemotherapy—the same population being evaluated in the phase III study.

Given the Company’s focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in a collaboration strategy to expand development of the product candidate in parallel with its priority development pathways. Pursuant to this strategy, in 2019 Nanobiotix entered into a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center to sponsor several phase I and phase II studies evaluating NBTXR3 across tumor types and therapeutic combinations. In 2023 Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV, a Johnson & Johnson company.

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, and Germany. Nanobiotix has been listed on Euronext: 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

Disclaimer

This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the use of proceed therefrom, and the period of time through which the Company's anticipates its financial resources will be adequate to support operations. Words such as "expects", "intends", "can", "could", "may", "might", "plan", "potential", "should" and "will" or the negative of these and similar expressions are intended to identify forward-looking statements. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management. These forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from those implied by the forward-looking statements, including risks related to Nanobiotix's business and financial performance, which include the risk that assumptions underlying the Company's cash runway projections are not realized. Further information on the risk factors that may affect company business and financial performance is included in Nanobiotix's Annual Report on Form 20-F filed with the SEC on April 24, 2023 under "Item 3.D. Risk Factors", in Nanobiotix's 2022 universal registration document filed with the AMF on April 24, 2023 as updated by its first amendment filed with the AMF on November 1st, 2023 and its second amendment filed with the AMF on November 3rd, 2023, in Nanobiotix's half-year report, which was filed with the SEC on Form 6-K and with the AMF on September 26, 2023, and subsequent filings Nanobiotix makes with the SEC from time to time which are available on the SEC's website at www.sec.gov. The forward-looking statements included in this press release speak only as of the date of this press release, and except as required by law, Nanobiotix assumes no obligation to update these forward-looking statements publicly.

Contacts

Nanobiotix

Communications Department
Brandon Owens
VP, Communications
+1 (617) 852-4835
contact@nanobiotix.com

Investor Relations Department
Craig West
SVP, Investor Relations
+1 (617) 583-0211
investors@nanobiotix.com

Media Relations

FR – **Ulysse Communication**
Pierre-Louis Germain
+ 33 (0) 6 64 79 97 51
plgermain@ulysse-communication.com

Global – **LifeSci Advisors**
Kevin Gardner
+1 (617) 283-2856
kgardner@lifesciadvisors.com

Attachment

- 2024-04-02 -- NBTX -- Completes Dose Escalation Part of Ph1 of NBTXR3 for NSCLC -- FINAL