Nanobiotix Announces First Data From the Completed Dose Escalation Part of a Phase 1 Study Evaluating NBTXR3 (JNJ-1900) as a 2L+ Therapy for Patients With Locally Advanced NSCLC

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- Data show favorable safety and confirm injection feasibility in 12 patients with locally advanced NSCLC amenable to re-irradiation for whom prior lines of therapy have failed
- A preliminary review of survival data showed 12-month LPFS of 64% (median 18.6 months) and 12-month OS of 83% (median 30.2 months)
- The dose escalation part is complete, and 5/12 patients have been injected to date in the ongoing expansion part

PARIS and CAMBRIDGE, Mass., March 27, 2025 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO — NASDAQ: NBTX – the " **Company**"), a late-stage clinical biotechnology company pioneering disruptive, nanotherapeutic approaches to revolutionize treatment outcomes for millions of patients, today announced the first data from the completed dose escalation part of a Phase 1 study sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") evaluating radiotherapy-activated NBTXR3 (JNJ-1900)[1] as a second or later line (2L+) therapy for patients with locally advanced non-small cell lung cancer ("NSCLC") amenable to re-irradiation. These data will be presented at the 2025 European Lung Cancer Conference by study principal investigator Dr. Saumil Gandhi.

ABSTRACT #207P: Phase 1 Study of Reirradiation ("ReRT") with NBTXR3 (JNJ-1900) for Inoperable Locoregional Recurrent Non-Small Cell Lung Cancer ("NSCLC")
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Locoregional recurrence occurs in 30-40% of patients with locally advanced NSCLC after treatment with definitive chemoradiation. Historically, patients who are amenable to re-irradiation are often limited to palliative doses due to associated toxicities. As such, strategies to enhance the therapeutic ratio of radiotherapy are needed to improve treatment outcomes.

"Patients with recurrence after prior radiation therapy for locally advanced lung cancer face limited therapeutic options and significant challenges in achieving durable disease control," said Saumil Gandhi, MD, PhD, Department of Thoracic Radiation Oncology, Division of Radiation Oncology at MD Anderson. *"These data underscore the need for continued therapeutic innovation for these patients and highlight the potential of NBTXR3 (JNJ-1900) as a novel approach to improving patient outcomes."*

Results from the completed dose escalation part of the study demonstrated a favorable safety profile with no dose-limiting toxicities (DLTs), and no Grade 3 or higher SAEs related to NBTXR3. Injection feasibility was confirmed, and the recommended phase 2 dose (RP2D) was established at 33% of gross tumor volume.

Promising early efficacy signals were observed. Preliminary review of survival data from 12 patients showed 12-month LPFS of 64% (median 18.6 months) and 12-month OS of 83% (median 30.2 months), further supporting the potential clinical benefit of NBTXR3 (JNJ-1900) in this patient population.

"The Nanobiotix team is encouraged by these early findings, which suggest NBTXR3 (JNJ-1900) could offer a new therapeutic option for patients with no alternatives after prior treatments have failed," said Louis Kayitalire, MD, Nanobiotix Chief Medical Officer. *"Notably, these results were observed in patients who resisted prior curative radiation doses and that were treated with JNJ-1900 (NBTXR3) activated by a lower radiation dose. As we advance the study's expansion phase, we look forward to further evaluating NBTXR3 (JNJ-1900)'s potential to improve patient outcomes."*

The expansion phase of the study is ongoing, with 5/12 patients injected to date.

About JNJ-1900 (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 3 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 3 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 1 and Phase 2 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 and is listed on Euronext Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020. The Company has subsidiaries in Cambridge, Massachusetts (United States) amongst other locations.

Nanobiotix is the owner of more than 25 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.

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 the Company' 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, 2024 under "Item 3.D. Risk Factors", in Nanobiotix's 2023 universal registration document filed with the AMF on April 24, 2024, in Nanobiotix' 2024 semi-annual report under the caption "Supplemental Risk Factor" filed with the SEC on Form 6-K and with AMF on September 18, 2024, 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.

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[1] Potential first-in-class radioenhancer "NBTXR3" was licensed to Johnson & Johnson by Nanobiotix in 2023 and renamed "JNJ-1900" for the purposes of Johnson & Johnson-led clinical development.

Attachment

- 2025-03-27 -- NBTX -- 1st Data from Ph1 of NBTXR3 in 2nd Line NSCLC -- FINAL