NANOBIOTIX Announces Complete Full Cohort Phase 1 Results for JNJ-1900 (NBTXR3) in Inoperable, Recurrent Non-Small Cell Lung Cancer

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- **All 24 patients completed treatment with no dose-limiting toxicities, no Grade 3 or higher adverse events related to JNJ-1900 (NBTXR3 or to the injection procedure, and intratumoral injection was deemed feasible**
- **One-year locoregional control rate was 79%, one-year local progression-free survival (LPFS) was 61%, and one-year overall survival (OS) was 70% in evaluable subjects—achieved at a lower re-irradiation dose than patients' prior course of radiotherapy**
- **Investigators concluded that JNJ-1900 (NBTXR3 may permit clinically meaningful local control using a substantially lower re-irradiation dose than patients' prior course of radiotherapy**
- **Enrollment in the dose-escalation and expansion parts of the study is complete per protocol; following the encourage findings, additional patient enrollment in this study is planned**

Data presented at the IASLC 2026 World Conference on Lung Cancer

PARIS and CAMBRIDGE, Mass., Sept. 14, 2026 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO - NASDAQ: NBTX - the "Company"), a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer and other major diseases, today announced updated safety and efficacy data from the completed dose-escalation and expansion phases of a Phase 1 study sponsored by The University of Texas MD Anderson Cancer Center ("UT MD Anderson") evaluating radiotherapy-activated JNJ-1900 (NBTXR3) for patients with inoperable, locoregionally recurrent non-small cell lung cancer ("NSCLC") amenable to re-irradiation ("reRT"). The data were presented by study principal investigator Saumil Gandhi, MD, PhD, at the International Association for the Study of Lung Cancer ("IASLC") 2026 World Conference on Lung Cancer ("WCLC"), taking place September 12–15, 2026 in Seoul, Republic of Korea.

POSTER P2.260: Re-irradiation (ReRT) with NBTXR3 for Inoperable Locoregionally Recurrent Non-Small Cell Lung Cancer (NSCLC): A Phase I Trial

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Patients who are candidates for re-irradiation are frequently limited to palliative radiation doses because of normal-tissue tolerance, and their recurrent tumors typically harbor the most radiation-resistant cells. Effective strategies to safely deliver radiotherapy doses capable of controlling recurrent tumors remain a significant unmet need in this setting.

"Recurrence within a previously irradiated field is one of the least forgiving problems in thoracic oncology," said Saumil Gandhi, MD, PhD, Department of Thoracic Radiation Oncology, Division of Radiation Oncology at UT MD Anderson. *"The normal tissue near the tumor has already received a full course of radiation, so the dose that can delivered safely during a second course is limited. Additionally, the disease that returns is often more radioresistant because it survived radiation the first time. In this study, JNJ-1900 (NBTXR3) was delivered without dose-limiting toxicities, and we observed clinically meaningful local control at a substantially lower re-irradiation dose. These findings warrant evaluation in a randomized trial."*

Results from the pooled dose-escalation and expansion phases showed that all 24 patients completed treatment with JNJ-1900 (NBTXR3) plus re-irradiation with no dose-limiting toxicities. Investigators reported no Grade 3 or higher adverse events related to JNJ-1900 (NBTXR3) or to the injection procedure.

Grade 3 radiotherapy-related adverse events occurred in 33% of patients (n=8), and Grade 5 radiotherapy-related adverse events in 8% (n=2). The recommended Phase 2 dose was established at 33% of gross tumor volume.

At a median follow-up of 12 months (data cutoff: August 2026) the one-year locoregional control rate was 79%. One-year local progression-free survival ("LPFS") was 61% (median 13.6 months), and one-year overall survival ("OS") was 70% (median 14.8 months). Investigators concluded that JNJ-1900 (NBTXR3) may permit clinically meaningful local control using a substantially lower re-irradiation dose.

"The Nanobiotix team is encouraged by these full-cohort findings in one of the most difficult settings in lung cancer," said Louis Kayitalire, MD, Chief Medical Officer of Nanobiotix. *"If a physics-based approach can improve local control in tissue that has already failed radiation, and do so at a reduced dose, then the conditions in earlier settings, where full-dose radiotherapy reaches previously untreated tissue, could be even more favorable. We look forward to further evaluation in additional patients enrolled to this study and across indications."*

Enrollment in both the dose-escalation and expansion parts of the study is complete per protocol. Following the encouraging findings, additional patient enrollment in this study is planned.

About JNJ-1900 (NBTXR3)

JNJ-1900 (NBTXR3) is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles administered via one-time intratumoral injection and activated by radiotherapy. The product candidate's 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. Proof-of-concept was demonstrated in a randomized Phase 2/3 soft tissue sarcoma study sponsored by Nanobiotix in 2018.

Radiotherapy-activated JNJ-1900 (NBTXR3) is being evaluated across multiple solid tumor indications as a single agent or combination therapy. 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 JNJ-1900 (NBTXR3) across tumor types and therapeutic combinations.

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.

In 2023, Nanobiotix announced a license agreement for the global development and commercialization of JNJ-1900 (NBTXR3) with Janssen Pharmaceutica NV, a Johnson & Johnson company. Studies being led by Johnson & Johnson include NANORAY-312 (NCT04892173), a global, randomized Phase 3 study in platinum-based chemotherapy-ineligible, locally advanced head and neck squamous cell cancers; LUMIRAY (NCT07219212), a global, phase 1b, open-label study in locally advanced head and neck squamous cell cancers; and CONVERGE (NCT06667908), a phase 2, randomized, open-label, active-controlled study in locally advanced and unresectable Stage III non-small cell lung cancer (NSCLC).

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 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.

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 2, 2025 under "Item 3.D. Risk Factors", in Nanobiotix's 2024 universal registration document filed with the AMF on April 2, 2025 under "chapter 1.5 Risk Factors", and subsequent filings Nanobiotix makes with the SEC and AMF from time to time, including the Half-Year Report at June 30, 2025 which are available on the SEC's website at www.sec.gov and on the AMF's website at www.amf.org, 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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