



NANOBIOTIX Announces First Data From Phase 1 Study Evaluating JNJ-1900 (NBTXR3) for Patients With Esophageal Cancer

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- Treatment was well-tolerated and injection feasibility was confirmed in 13 patients with locally advanced adenocarcinoma of the esophagus
- 85% (11/13) disease control rate (DCR)
- 69% (9/13) objective response rate (ORR); 6 complete responses and 3 partial responses
- Recruitment of 17 additional patients is ongoing as planned

Data presented at the 2025 Annual Meeting of the American Society for Radiation Oncology (ASTRO) on October 1st

PARIS and CAMBRIDGE, Mass., Oct. 01, 2025 (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 first data from cohorts 1 and 2 of the dose escalation part of a Phase 1 dose escalation and dose expansion study evaluating JNJ-1900 (NBTXR3) combined with photon chemoradiation (cohort 1) or proton chemoradiation (cohort 2) followed by surgery, if medically indicated, for patients with locally advanced adenocarcinoma of the esophagus (“EADC”). The study is sponsored by The University of Texas MD Anderson Cancer Center (“MD Anderson”) and results were presented by Principal Investigator Steven Lin, MD, PhD, Professor of Radiation Oncology at MD Anderson at the 2025 Annual Meeting of the American Society for Radiation Oncology (ASTRO).

ABSTRACT # 1113: ENDOSCOPIC ULTRASOUND FINE NEEDLE INJECTION OF NBTXR3 ACTIVATED BY RADIOTHERAPY WITH CONCURRENT CHEMOTHERAPY FOR ADENOCARCINOMA OF THE ESOPHAGUS: FEASIBILITY AND SAFETY OF THE PHASE 1 DOSE ESCALATION PART FOR THE PHOTON-BASED COHORT

Steven H. Lin, Emmanuel Coronel, Saumil Gandhi, Julianna Bronk, David Qian, Joe Y. Chang, Michael O'Reilly, Matthew Ning, Aileen Chen, Quynh Nguyen, James Welsh, Diana Amaya, Christina Hoang, Wayne Hofstetter, Mariela Blum-Murphy, Albert C. Koong, Zhongxing Liao
MD Anderson Cancer Center, Houston, Texas, USA

Esophageal cancer is the eighth most common cancer worldwide with an estimated 572,000 new cases and 508,600 deaths each year. Radiotherapy is a cornerstone of treatment and neoadjuvant chemoradiotherapy (“CRT”) followed by surgery is the standard of care. However, there is some controversy as to whether the toxicities of neoadjuvant CRT will lead to increased postoperative complications. Moreover, surgical removal of large segments of the esophagus (esophagectomy) is associated with significant comorbidities and negative impact on patients’ quality of life. Treatment strategies that enhance local control, reduce the need for surgery, and improve survival outcomes are an important unmet need.

“Esophageal cancer remains one of the most difficult contexts for both patients and clinicians, where existing standards of care can create significant burdens for patients,” said Louis Kayitalire, Chief Medical Officer at Nanobiotix. *“We believe that JNJ-1900 (NBTXR3), through its broadly applicable mechanism of action, could offer a novel approach—one designed to enhance local control and potentially reduce the need for highly invasive procedures such as esophagectomy.”*

Safety and Feasibility

Treatment was well-tolerated and feasible in the study population (n=13):

- Feasibility of endoscopic ultrasound-guided intratumoral injection was confirmed in 9 EADC patients with treated JNJ-1900 (NBTXR3) combined with photon CRT in cohort 1 and 4 EADC patients treated with JNJ-1900 (NBTXR3) combined with proton CRT in cohort 2
- The recommended Phase 2 dose (“RP2D”) for JNJ-1900 (NBTXR3) combined with photon CRT was established at 33% of gross tumor volume (GTV)
- In total, 13 patients experienced treatment-emergent adverse events (“TEAEs”) of any grade related to the overall treatment (Chemotherapy, RT, JNJ-1900 (NBTXR3), and injection procedure)
 - Of which, 6 patients experienced TEAEs of any grade (1, 2, or 3+) related to JNJ-1900 (NBTXR3) and 2 patient experienced TEAEs of any grade related to the injection procedure
 - Of these patients, 2 experienced grade 3+ TEAEs related to JNJ-1900 (NBTXR3) and 0 experienced grade 3+ TEAEs related to the injection procedure
- No periprocedural or delayed adverse events were observed

Signals of Efficacy

Promising initial clinical response and outcomes:

- 85% (11/13) disease control rate (DCR)
- 69% (9/13) objective response rate (ORR), including 6 biopsy-confirmed complete responses (CRs) and 3 partial responses (PRs)
- 6 patients in the study were medically indicated for and underwent surgery after treatment with CRT and JNJ-1900 (NBTXR3)
 - 2 of these patients had pathological complete response (pCR)
 - 4 of these patients had major pathologic response ($\leq 10\%$ viable cells)

“These early results support our hypothesis that intratumoral injection of JNJ-1900 (NBTXR3) in combination with chemoradiation is both technically feasible and generally well-tolerated in patients with locally advanced esophageal adenocarcinoma,” said Steven Lin, MD, PhD, Professor of Radiation Oncology at MD Anderson. *“Importantly, we observed encouraging rates of disease control and complete response that suggest this novel approach could help improve local tumor control while potentially sparing patients from the risks and long-term consequences of esophagectomy. These early findings provide a strong foundation for further investigation.”*

Importantly, this evaluation in locally advanced esophageal cancer could potentially open a new indication for JNJ-1900 (NBTXR3) and provide support for the investigational radioenhancer in combination with proton radiation therapy as an additional activation modality beyond standard (photon) radiation therapy. Recruitment for dose escalation cohort 1 is complete. 5 additional patients are being recruited for dose escalation cohort 2, which will be followed by recruitment of 12 additional patients for the dose expansion part of the study.

About JNJ-1900 (NBTXR3)

JNJ-1900 (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 through a successful randomized Phase 2/3 study in 2018. 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. Given the physical MoA, Nanobiotix believes that JNJ-1900 (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 JNJ-1900 (NBTXR3) is being evaluated across multiple solid tumor indications as a single agent or combination therapy. The program is led by 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 JNJ-1900 (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 JNJ-1900 (NBTXR3) across tumor types and therapeutic combinations. In 2023, Nanobiotix announced a license agreement for the global co-development and commercialization of JNJ-1900 (NBTXR3) with Janssen Pharmaceutica NV, a Johnson & Johnson company.

About NANOBOTIX

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 proceeds 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’s 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.

Contacts

Communications Department

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

Investor Relations Department

Joanne Choi
VP, Investor Relations (US)
+1 (713) 609-3150
investors@nanobiotix.com

Ricky Bhajun
Director, Investor Relations (EU)
+33 (0) 79 97 29 99
investors@nanobiotix.com

Media Relations

France – **HARDY**
Caroline Hardy
+33 06 70 33 49 50
carolinehardy@outlook.fr

Global – **uncapped Communications**
Becky Lauer
+1 (646) 286-0057
nanobiotixteam@uncappedcommunications.com

Attachment

- [2025-10-01 -- NBTX -- Ph1 NBTXR3 Data in EADC -- FINAL](#)