



NANOBIOTIX Announces Final Data from Phase 1 Study Evaluating JNJ-1900 (NBTXR3) With Immune Checkpoint Inhibitors as a 2L+ Therapy in Anti-PD-1-Resistant Primary Cutaneous Melanoma

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- **In 24 heavily pre-treated patients with advanced primary cutaneous melanoma whose cancer had progressed after multiple prior lines of therapy including anti-PD-1 therapy, data continue to show an acceptable safety profile and early signals of efficacy**
- **41.7% (10/24) overall response rate (ORR) per RECIST 1.1, including 4 complete responses**
- **75% (18/24) disease control rate (DCR)**
- **17.8 months median Overall Survival**
- **Exploratory analysis in a subset of patients (n=8) identified IL-1 β , a cytokine linked to treatment-induced anti-tumor immunity, as the most increased plasma cytokine after treatment**
- **Investigators concluded that these preliminary findings warrant further evaluation in randomized clinical trials for patients with primary cutaneous melanoma naïve or refractory to anti-PD-1**

Data presented at the 2026 Congress of the European Society for Medical Oncology

PARIS and CAMBRIDGE, Mass., Oct. 24, 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 results from patients with anti-PD-1-resistant advanced primary cutaneous melanoma treated in the ongoing Phase 1 Study 1100. The study evaluates JNJ-1900 (NBTXR3), which works in the presence of radiotherapy, followed by an immune checkpoint inhibitor (nivolumab or pembrolizumab) in patients with advanced solid tumors. The data were presented by Jason Chan, MD, Associate Professor, Department of Radiation Oncology, UCSF Helen Diller Family Comprehensive Cancer Center, in a poster session on Saturday, October 24, 2026, at the 2026 Annual Meeting of the European Society for Medical Oncology ("ESMO") in Madrid, Spain.

ABSTRACT #3956: Safety and Anti-Tumor Activity of NBTXR3/SBRT with Immune Checkpoint Inhibitors in Anti-PD-1 Resistant Melanoma: Results from a Phase I Dose Expansion

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Patients with advanced anti-PD-1 resistant primary cutaneous melanoma whose disease has progressed after multiple prior lines of therapy have a poor prognosis; published series report a median progression-free survival of approximately three months¹ and a median overall survival of approximately one year² in this setting. Melanoma has historically been considered radioresistant, and higher radiation doses are often limited by exposure of the surrounding healthy tissue.

"Patients whose melanoma has progressed on anti-PD-1 therapy, and often on several other immunotherapies as well, have limited options left," said Jason Chan, MD, Associate Professor, Department of Radiation Oncology, UCSF Helen Diller Family Comprehensive Cancer Center "In this study, a single injection followed by a short course of stereotactic radiotherapy was feasible across a wide range of tumor sizes and locations, and we saw responses in lesions that were injected and in lesions that were not. The observed increase in IL-1 β suggests treatment-related immune activation that warrants further investigation. These are early data from a single-arm study, and they support testing the approach in a randomized trial."

All 24 heavily pre-treated patients had advanced primary cutaneous melanoma resistant to anti-PD-1; 14 had stage IV disease. Most had received other immunotherapies before enrolling, including anti-CTLA-4 (50%), anti-LAG-3 (33.3%) and T-VEC (25%), and 87.5% had received immunotherapy as their most recent therapy. Patients received a one-time intratumoral injection of JNJ-1900 (NBTXR3) at the recommended Phase 2 dose (33% of gross tumor volume), followed by stereotactic body radiotherapy ("SBRT") to the injected lesion and then nivolumab or pembrolizumab. Investigators observed an acceptable safety profile and early signals of efficacy.

Safety and Feasibility

Treatment consisting of a single intratumoral JNJ-1900 (NBTXR3) injection, followed by a short course of radiotherapy was feasible across a wide range of melanoma lesions, providing a minimally invasive treatment approach with an acceptable safety profile. No new safety signals have been

observed.

Preliminary Efficacy

An Overall Response Rate (ORR) of 41.7% (10/24 patients) was observed. Responses were observed in both injected (ORR 45.8%; 11/24 evaluable patients) and non-injected lesions (ORR 30.0%; 3/10 evaluable patients).

Median Progression Free Survival (PFS) was 6.9 months, while median Overall Survival reached 17.8 months.

Exploratory Immune Profiling

In an exploratory analysis of plasma samples from a subset of patients (n=8), IL-1 β showed the largest increase from baseline among the cytokines evaluated. Published research has linked IL-1 β to treatment-induced anti-tumor immunity through its role in connecting innate immune activation to the priming of tumor-specific CD8+ T cells.³

"This updated analysis, with more patients and longer follow-up, builds on the first data we reported with consistent safety and an improvement in Overall Survival relative to the first data reported," said Louis Kayitalire, MD, Chief Medical Officer of Nanobiotix. "Responses were again seen in patients whose disease had progressed after multiple prior therapies, including in lesions that were not injected. Together with the exploratory cytokine data, these findings warrant further evaluation of JNJ-1900 (NBTXR3) followed by anti-PD-1 therapy in patients with anti-PD-1-resistant melanoma."

Overall, the acceptable safety profile and early efficacy observed by investigators in these preliminary findings provide promising signals of activity and warrant further evaluation in larger randomized trials.

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 designed to work in the presence of radiotherapy. The product candidate's mechanism of action (MoA) is designed to induce significant tumor cell death in the injected tumor when in the presence of 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.

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 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 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 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

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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 March 31, 2026 under "Item 3.D. Risk Factors", in Nanobiotix's 2025 universal registration document filed with the AMF on March 31, 2026 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, 2026, 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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¹Patrinely JR Jr., *Cancer*. 2020

²Nordstrom BL, *Future Oncol*. 18:1343-1355, 2022

³Ghiringhelli et al. *Nat Med*. 15(10):1170-8, 2009

Attachment

- [PR_Study 1100 Melanoma Data ESMO 2026](#)