NANOBIOTIX Announces New Results From a Phase 1 Study Evaluating JNJ-1900 (NBTXR3) in Combination With Immune Checkpoint Inhibitors as a 2L+ Therapy for Patients With Primary Cutaneous Melanoma Resistant to Anti-PD-1

September 17, 2025 8:15 PM EDT

- Data show a favorable safety profile and early efficacy signals in a heavily pre-treated population whose cancer progressed after multiple prior lines of therapy including anti-PD-1
- Recommended phase 2 dose (RP2D) established at 33% of gross tumor volume (GTV)
- 47.4% (9/19) best observed objective response rate (ORR) in all lesions per RECIST 1.1
- 78.9% (15/19) best observed disease control rate (DCR) in all lesions per RECIST 1.1
- 14.6 months median Overall Survival (mOS) in all patients treated (n=21)
- Investigators concluded that these data warrant further investigation in randomized clinical trials as a potential new option for patients with primary cutaneous melanoma naïve or refractory to anti-PD-1
- Nanobiotix will host a conference call to discuss the data on September 18, 2025 at 8:00AM EDT/ 2:00PM CEST

Data presented on September 17 at the 2025 Immunorad Conference

PARIS and CAMBRIDGE, Mass., Sept. 17, 2025 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO — NASDAQ: NBTX – the " **Company**"), a late-clinical stage biotechnology company pioneering nanotherapeutic approaches to expand treatment possibilities for patients with cancer and other major diseases, today announced new results focused on patients with primary cutaneous melanoma from the ongoing Phase 1 Study 1100 evaluating JNJ-1900 (NBTXR3) in combination with immune checkpoint inhibitors (pembrolizumab or nivolumab) for patients with advanced cancers. These findings were presented at the 2025 ImmunoRad conference in Paris, France on September 17.

Patients with anti-PD-1 resistant primary cutaneous melanoma in the study had advanced disease that progressed despite multiple prior lines of therapy, including anti–PD-1, ipilimumab, T-VEC, TIL, and radiotherapy ("RT"), among others. All patients received a one-time intratumoral injection of JNJ-1900 (NBTXR3) followed by RT and sequential anti–PD-1 therapy. As of the August 21, 2025, data cutoff, 21 patients had been injected with JNJ-1900 and 19 were evaluable for tumor response (2 patients were not evaluable due to lack of post-treatment imaging).

"The patients in this analysis represent one of the more difficult clinical challenges we face as many have exhausted standard therapies, including checkpoint inhibitors," said Study 1100 Coordinating Investigator Colette Shen, MD, PhD, Assistant Professor of Radiation Oncology, University of North Carolina Lineberger Comprehensive Cancer Center. *"While these data are preliminary, the responses we're seeing provide a strong signal that this treatment approach could potentially offer a new possibility for patients who need more options."*

Safety and Feasibility

All 21 patients with primary cutaneous melanoma had shown prior resistance to anti-PD-1 and treatment with RT-activated JNJ-1900 (NBTXR3) followed by anti-PD-1 showed a favorable safety profile:

- Injection feasibility was confirmed at the recommended Phase 2 dose (33% GTV)
- In total, 16 patients experienced grade 1, grade 2, or grade 3+ TEAEs related to the overall therapeutic regimen (RT, anti-PD-1, JNJ-1900 (NBTXR3), and injection procedure)
- Of which 5 patients experienced grade 1, grade 2, or grade 3+ treatment-emergent adverse events (TEAEs) related to JNJ-1900 (NBTXR3) and/or the injection procedure
    - Of these patients, 1 patient experienced grade 3+ TEAEs (hypotension and pleuritic pain)

Early Signs of Efficacy

JNJ-1900 (NBTXR3) demonstrated preliminary signals of efficacy in 19 patients who were evaluable for tumor response:

- A best observed objective response rate ("ORR") in all lesions of 47.4% (9/19) per RECIST 1.1, including 4 complete responses and 5 partial responses
- A best observed disease control rate ("DCR") in all lesions of 78.9% (15/19) per RECIST 1.1

- In JNJ-1900 injected & irradiated tumors, a DCR of 100% (19/19) was observed
- A median Overall Survival (mOS) of 14.6 months [95% CI: 10.7 months; 16.7 months] in all patients treated (n=21)

Notably, a relationship was observed between the depth of local response and systemic tumor regression, suggesting a possible priming or re-activation of immune response.

"We are encouraged by these new findings and the potential signals of activity in this difficult-to-treat population," said Louis Kayitalire, MD, Chief Medical Officer of Nanobiotix. *"Notably, the relationship we observed between the depth of local response and systemic tumor regression further supports our hypothesis regarding the potentially broad applicability of JNJ-1900 (NBTXR3) for patients with cancer. We look forward to further clinical evaluation of JNJ-1900 (NBTXR3) to better understand its capacity to drive both local and systemic responses in primary cutaneous melanoma."*

Nanobiotix Conference Call

Nanobiotix will host a conference call and webcast featuring Nanobiotix chief executive officer, Laurent Levy, to discuss the new data on Thursday, September 18th, 2025, at 8:00 AM EDT / 2:00 PM CET.

Details for the call are as follows:

Webcast link: https://edge.media-server.com/mmc/p/afhekjqh

Audio-only dial-in link: https://register-conf.media-server.com/register/Bicf7d5819d70446639d58b5a5867cf216

Participants can use the audio-only link above to register and obtain dial-in instructions to listen to the presentation via phone and ask questions during the Q&A session, or participants can use the webcast link to register and listen and watch the slide presentation online; the replay version will be available under the same webcast link shortly after the presentation and will be archived on the Company's website at www.nanobiotix.com. It is recommended to join 10 minutes prior to the event start. Participants are invited to email their questions in advance to investors@nanobiotix.com.

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 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 02, 2025 under "Item 3.D. Risk Factors", in Nanobiotix's 2024 universal registration document filed with the AMF on April 02, 2025, 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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Attachment

- 2025-09-17 -- NBTX -- +New Ph1 NBTXR3 Data in Combo w-ICI -- FINAL