NANOBIOTIX Announces Updated Phase 1 Results Continuing to Support JNJ-1900 (NBTXR3) Plus Anti-PD-1 as a Potential New 1L or 2L+ Option in Anti-PD-1 Naïve or Resistant R/M-HNSCC

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- Treatment remained well-tolerated with consistent injection feasibility in 103 heavily pre-treated patients with R/M-HNSCC naïve or resistant to anti-PD-1
- 63% (26/41) disease control rate ("DCR") and 37% (15/41) objective response rate ("ORR") in evaluable anti-PD-1 naïve patients per RECIST 1.1
- 74% (37/50) DCR and 32% (16/50) ORR in evaluable anti-PD-1 resistant patients per RECIST 1.1
- 15.5 months median Overall Survival ("mOS") in evaluable anti-PD-1 naïve patients
- 11.4 months mOS in evaluable anti-PD-1 resistant patients
- Investigators concluded that these promising results warrant further exploration in randomized controlled trials

Data presented as a "Top-rated Abstract in Head and Neck Cancer" at the 2025 Annual Meeting of the American Society for Radiation Oncology (ASTRO) on September 29th

PARIS and CAMBRIDGE, Mass., Sept. 29, 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 updated data from cohorts 1 and 2 of Study 1100, a multicenter Phase 1 dose escalation and expansion trial evaluating JNJ-1900 (NBTXR3) activated by radiation therapy ("RT") followed by anti-PD-1 immune checkpoint inhibitors (pembrolizumab or nivolumab; "ICIs") in patients with recurrent and/or metastatic head and neck squamous cell carcinoma ("R/M-HNSCC") that is naïve (cohort 1) or resistant (cohort 2) to prior anti-PD-1 therapy. Study results were presented as a "Top-rated Abstract in Head and Neck Cancer" by Study 1100 Coordinating Investigator Colette Shen, MD, PhD, Assistant Professor of Radiation Oncology, University of North Carolina Lineberger Comprehensive Cancer Center, at the 2025 Annual Meeting of the American Society of Radiation Oncology (ASTRO).

ABSTRACT #245: PHASE 1 DOSE ESCALATION/DOSE EXPANSION TRIAL OF NBTXR3/SBRT IN COMBINATION WITH NIVOLUMAB OR PEMBROLIZUMAB FOR TREATMENT OF ANTI-PD-1 NAÏVE OR RESISTANT PATIENTS WITH RECURRENT/METASTATIC HEAD AND NECK SQUAMOUS CELL CARCINOMA

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The efficacy of ICI monotherapy remains limited in R/M-HNSCC, with objective response rates between approximately 13% and 18%, and median Overall Survival ("mOS") between approximately 8 months and 12 months. As approximately 66% of patients with R/M-HNSCC experience disease recurrence locally or loco-regionally, addition of RT to the treatment regimen is often recommended to improve local control and as a potential option for stimulating immune responses. However, to date, the addition of RT has not significantly improved ICI efficacy in R/M-HNSCC. As such, patients with R/M-HNSCC have an unmet need for novel treatment strategies that can improve local tumor control and potentiate systemic immune response.

Safety and Feasibility

JNJ-1900 (NBTXR3) activated by RT followed by anti-PD-1 was consistently well-tolerated and remained feasible in this heavily pre-treated patient population (n=103):

- Injection remained consistently feasible at the recommended Phase 2 dose (33% GTV)
- Favorable safety profile including no additional toxicities in lesions that were injected after re-irradiation
- 27 patients experienced treatment-emergent adverse events (TEAEs) of any grade (1, 2, or 3+) related to JNJ-1900 (NBTXR3) and 32 patients experienced TEAEs of any grade related to the injection procedure
    - Of these patients, 5 experienced grade 3+ TEAEs related to JNJ-1900 (NBTXR3) and 4 experienced grade 3+ TEAEs related to the injection procedure

- In total, 71 patients experienced TEAEs of any grade related to the overall therapeutic regimen
- Patients were deemed non-evaluable for efficacy (n=12) if more than one RT session was missed and/or a post-treatment tumor response assessment was unavailable

Signals of Efficacy

Potential enhancement of local responses:

- Evaluable Anti-PD-1 Naïve Patients (n=41)
  - Injected-lesion Disease Control Rate (“DCR”): 95% (39/41)
  - Injected-lesion Overall Response Rate (“ORR”): 66% (27/41)
  - Local Progression-free Survival (“LPFS”): 34.4 months [95% CI: 12.8; Not Reached]
- Evaluable Anti-PD-1 Resistant Patients (n=50)
  - Injected-lesion DCR: 94% (47/50)
  - Injected-lesion ORR: 50% (25/50)
  - LPFS: 7.3 months [95% CI: 5.7; Not Reached]

Systemic responses beyond potential enhanced local control:

- Evaluable Anti-PD-1 Naïve Patients
  - DCR per RECIST 1.1: 63% (26/41)
  - ORR per RECIST 1.1: 37% (15/41)
- Evaluable Anti-PD-1 Resistant Patients
  - DCR per RECIST 1.1: 74% (37/50)
  - ORR per RECIST 1.1: 32% (16/50)

Early signals of Overall Survival that is expected to mature with additional follow up:

- Evaluable Anti-PD-1 Naïve Patients
  - Median Overall Survival: 15.5 months [95% CI: 11.0; Not Reached]
- Evaluable Anti-PD-1 Resistant Patients
  - Median Overall Survival: 11.4 months [95% CI: 7.8; 16.7]

Notably, survival data in anti-PD-1 resistant patients suggests JNJ-1900 (NBTXR3) activated by RT followed by anti-PD-1 may overcome prior resistance to immune checkpoint inhibitors. Overall, these results show strong local control, with an aggregate DCR of 95% (86/91) in JNJ-1900 (NBTXR3)-injected lesions in evaluable patients, representing a critical potential outcome for patients with R/M-HNSCC. Moreover, the results suggest that the antitumoral activity of JNJ-1900 (NBTXR3) activated by RT may occur beyond the injected lesion. Investigators concluded that these promising results warrant further exploration in randomized controlled trials.

“Through the evaluation of JNJ-1900 (NBTXR3) cohorts 1 and 2 of Study 1100, we are ensuring that we prioritize the clinical development of innovation that acts both locally and systemically to address the unmet needs of patients with R/M-HNSCC,” said Study 1100 Coordinating Investigator Colette Shen, MD, PhD. *“Our findings from Study 1100 have consistently supported a well-tolerated safety profile with early efficacy signals, and I look forward to further investigation of JNJ-1900 (NBTXR3) as a potentially new and complementary therapeutic option for patients."*

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 Johnson & Johnson.

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

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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 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

- 2025-09-29 -- NBTX -- Updated Ph1 Results for NBTXR3 -- FINAL