



Nanobiotix Announces Full Results From Completed Phase 1 Study Evaluating JNJ-1900 (NBTXR3) in Pancreatic Cancer

May 5, 2025 6:00 AM EDT

- Results demonstrated favorable safety, injection feasibility, and encouraging oncologic outcomes in patients (n=22) with locally advanced or borderline resectable pancreatic cancer
- Median Overall Survival of 23 months from date of diagnosis [95% CI; 17 months – not reached]
- Median Local Progression-Free Survival of 13.3 months from completion of radiation
- Notable findings observed in exploratory biomarker analyses include:
 - An association between increased circulating tumor mutational burden (cTMB) and LPFS and OS
 - CA19-9 normalization in 59% of patients in the study, and an association between CA19-9 normalization and OS
- First patient injected in a new cohort that adds standard-of-care concurrent chemotherapy (capecitabine or 5-FU) to radiotherapy-activated JNJ-1900 (NBTXR3) and recruitment is ongoing
- Investigators concluded that these results support further evaluation in a randomized study

Data presented at the 2025 Annual Meeting of the European Society of Radiation Oncology

PARIS and CAMBRIDGE, Mass., May 05, 2025 (GLOBE NEWSWIRE) -- [NANOBIOTIX](#) (Euronext: NANO — NASDAQ: NBTX — the “**Company**”), a late-stage clinical biotechnology company pioneering nanotherapeutic approaches to improve treatment outcomes for patients with cancer, today announced the presentation of full results from the completed dose escalation and dose expansion phases of a Phase 1 study evaluating JNJ-1900 (NBTXR3) in patients with locally advanced or borderline resectable pancreatic cancer. The study, conducted by The University of Texas MD Anderson Cancer Center (“MD Anderson”), was presented by principal investigator Dr. Eugene Koay at the 2025 Annual Meeting of the European Society for Radiotherapy and Oncology (ESTRO 2025).

Pancreatic ductal adenocarcinoma (PDAC) remains one of the most lethal malignancies, driven by aggressive tumor biology and limited responsiveness to standard therapies. For patients with locally advanced (“LAPC”) or borderline resectable (“BRPC”) disease, the current standard-of-care (“SOC”)—induction chemotherapy followed by chemoradiation—rarely delivers curative outcomes, underscoring the need for novel treatment approaches.

“Patients with locally advanced or borderline resectable pancreatic cancer face a particularly urgent unmet need for therapeutic innovation that can provide a meaningful survival benefit with an acceptable safety profile,” said Eugene Koay, MD, PhD, Associate Professor of Radiation Oncology at MD Anderson. *“We are encouraged by the results from the completed cohorts and look forward to the continued evaluation of JNJ-1900 (NBTXR3) in combination with standard-of-care chemoradiation after induction chemotherapy.”*

PRESENTATION #E25-2265: NANORAY Pancreas: A Phase 1 Study of NBTXR3 (JNJ-1900) Activated by Radiotherapy for Locally Advanced or Borderline Resectable Pancreatic Cancer (LAPC or BRPC)

Koay EJ, Liu S, Guerrero P, Stokes E, Katz MHG, Ikoma N, Snyder RA, Tzeng CD, Overman MJ, Pant S, Wolff RA, Javle M, Holliday EB, Ludmir EB, Das P, Noticewala S, Koong AC, Tamm EP, Bhutani M

This MD Anderson-sponsored Phase 1 study evaluated the potential of radiotherapy (“RT”)–activated JNJ-1900 (NBTXR3) activated by radiation therapy (45 Gy in 15 fractions) to overcome inherent radioresistance in patients with LAPC or BRPC. The majority of patients in the study (20/22) were diagnosed with locally advanced, unresectable disease (LAPC). For clarity, patients with LAPC or BRPC are traditionally treated with induction chemotherapy followed by concurrent chemoradiation. The treatment regimen in the completed dose escalation and dose expansion parts of this Phase 1 study replaced concurrent chemoradiation with RT-activated JNJ-1900 (NBTXR3) after induction chemotherapy.

Key Results:

- Favorable safety profile and injection feasibility were observed (n=22)
- Median overall survival (“mOS”): 23 months from diagnosis [95% CI; 17 months – not reached]
 - For context, an MD Anderson historical review of 144 patients with LAPC treated at the same center showed a mOS of 19.2 months. Patients in the historical review received induction chemotherapy followed by RT with or without concurrent or maintenance chemotherapy (80% received RT with concurrent chemotherapy)

- Median local progression-free survival (“mLPFS”): 13.3 months from completion of radiation
- Two LAPC patients achieved R0 surgical resection

Exploratory Biomarker Analyses:

- Of the 20 patients for whom circulating Tumor Mutational Burden (cTMB) data was available, a notable proportion (40%; 8/20) exhibited increased cTMB, and investigators observed an association between increased cTMB and improved LPFS and OS
- Normalization of CA19-9, a surrogate for overall survival benefit, was observed in 59% of patients (11/22) and was associated with longer survival in the study.
 - For context, an MD Anderson historical review of 243 patients with LAPC treated at the same center showed normalization of CA19-9 in approximately 17% of patients treated with the standard of care who had elevated CA19-9 levels at diagnosis

Based on the safety and preliminary efficacy findings, investigators concluded that further evaluation of JNJ-1900 (NBTXR3) is warranted in a randomized study.

“Our collaboration with MD Anderson has always been driven by a shared commitment to exploring bold new approaches for patients with high unmet need,” said Louis Kayitalire, MD, Chief Medical Officer at Nanobiotix. “Given the extremely poor survival rates in LAPC and BRPC, the results from this Phase 1 study give us confidence in the potential of JNJ-1900 (NBTXR3) to serve as a meaningful addition to the treatment landscape. We are particularly excited about the potential to further enhance outcomes through combination of JNJ-1900 (NBTXR3) with SOC chemoradiation in the study’s new active cohort, and we look forward to advancing this program in pancreatic cancer.”

MD Anderson received FDA clearance to expand the study to include a new cohort that combines of JNJ-1900 (NBTXR3) with SOC concurrent chemoradiation after induction chemotherapy. The first patient in the new cohort has been injected, and recruitment is ongoing.

Nanobiotix Conference Call

Nanobiotix will host a conference call and webcast featuring Nanobiotix Chief Executive Officer and Chairman of the Executive Board, Laurent Levy, to discuss the data on Monday May 5th, 2025, at 8:00 AM EDT / 2:00 PM CEST.

Details for the call are as follows:

Webcast link: [click here](#)

Audio-only dial-in link: [click here](#)

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 physical 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 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

- [2025-05-05 -- NBTX -- Full Ph1 NBTXR3 Results in Pancreatic Cancer -- FINAL](#)