



NANOBIOTIX Announces Updated Preliminary Results From Phase 1 Pancreatic Cancer Trial and New Exploratory Analysis From Completed Phase 1 Head and Neck Cancer Trial at ESMO 2023

October 23, 2023 6:00 AM EDT

Strategic Collaborator-presented Phase 1 Pancreatic Cancer Data

- *An ongoing Phase 1, collaborator-led study of NBTXR3 in locally advanced pancreatic cancer (LAPC) established a favorable safety profile and recommended dose*
- *23 months median Overall Survival (mOS) observed in 17 patients treated with cytotoxic chemotherapy followed by RT-activated NBTXR3*
- *Review of an historical control from the same center as this Phase 1 in 243 patients with LAPC showed an mOS of 19.2 months in 144 patients who received cytotoxic chemotherapy followed by RT with or without concurrent or maintenance chemotherapy (80% received RT with concurrent chemotherapy)*
- *The investigator concluded that these results suggest promising anti-tumor efficacy for NBTXR3 in LAPC*

Nanobiotix-presented Study 102 Exploratory Analysis

- *New exploratory analysis of completed Study 102 sought additional signs of efficacy in the evaluable population (n=44) as strong support for the hypotheses underlying the design of the Company's ongoing registrational Phase 3 study (NANORAY-312)*
- *42.8 months mOS observed in the 81.8% of evaluable patients who had complete or partial response in the NBTXR3-injected lesion (36/44) compared to 18.1 months in All Patients Treated (n=56)*
- *Analysis showed a positive correlation between Objective Response to RT-activated NBTXR3 in the injected lesion, along with injected-lesion Progression-Free Survival, and the extension of OS for elderly, frail patients with head and neck cancer*
- *These data suggest that the high rate of Objective Response to RT-activated NBTXR3 could potentially extend PFS and OS for elderly, frail patients with locally advanced head and neck cancer*

PARIS and CAMBRIDGE, Mass., Oct. 23, 2023 (GLOBE NEWSWIRE) -- **NANOBIOTIX** (Euronext: NANO — NASDAQ: NBTX – the “Company”), a late-clinical stage biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced updated data from two presentations at the 2023 Annual Congress of the European Society for Medical Oncology (ESMO).

POSTER #1631P: Phase 1 Study of Endoscopic Ultrasound (EUS)-guided NBTXR3 delivery activated by Radiotherapy (RT) for Locally Advanced or Borderline Resectable Pancreatic Cancer (LAPC or BRPC)

The 5-year overall survival rate for patients with unresectable locally advanced pancreatic cancer (LAPC) remains less than 5%. Normally, these patients receive the combination of cytotoxic chemotherapy followed by concurrent chemoradiation if no metastatic progression has occurred. Innovative new treatments that might extend survival and avoid additional harmful side effects are an urgent unmet need for this patient population.

With safety, feasibility, and the recommended Phase 2 dose (RP2D) previously determined and reported, this presentation from The University of Texas MD Anderson Cancer Center (MD Anderson) explored additional preliminary signals of efficacy from the ongoing Phase 1 study evaluating RT-activated NBTXR3 after cytotoxic chemotherapy for patients with LAPC to potentially inform next steps in clinical trial development.

An MD Anderson historical review of 243 patients treated with LAPC at the same center showed:

- Normalization of the biomarker CA19-9, a surrogate indicator for longer survival, in approximately 17% of patients treated with the standard of care who had elevated CA19-9 levels at diagnosis (n=183)
- Median Overall Survival (mOS) of 19.2 months in 144 patients who received cytotoxic chemotherapy followed by RT with or without concurrent or maintenance chemotherapy (80% received RT with concurrent chemotherapy)

Comparatively, preliminary data from 17 patients treated with cytotoxic chemotherapy followed by RT-activated NBTXR3 in the Phase 1 LAPC study show:

- Normalization of CA19-9 in 42% of patients who had elevated levels at diagnosis (n=12)
- An mOS of 23 months from diagnosis

The investigator concluded that these results suggest promising anti-tumor efficacy for NBTXR3 in LAPC.

"As we continue to execute our global development program for NBTXR3 across tumor types and therapeutic combinations in parallel with our collaborators, we view the consistently favorable safety profile for our localized therapeutic innovation as critical to the product candidate's potential," said Louis Kayitalire, MD, chief medical officer at Nanobiotix. *"Patients with locally advanced pancreatic cancer are faced with poor survival and quality of life outcomes, and these preliminary efficacy and favorable safety data are an exciting indicator that NBTXR3 may present a promising new option."*

ABSTRACT #5222: Antitumor Activity of the Radioenhancer NBTXR3 on Injected Lesions to Estimate Overall Survival: Exploratory Analyses from a Phase 1 in Cisplatin-Ineligible Locally Advanced HNSCC Patients

The previously reported final efficacy analysis of Study 102—a Phase 1 dose escalation and dose expansion study evaluating RT-activated NBTXR3 for elderly, frail patients with locally advanced head and neck cancer found that therapy was feasible, well tolerated with a favorable safety profile, and showed both prolonged Progression-Free Survival (PFS) and OS in a population characterized by negative prognostic factors.

This new exploratory analysis showed an mOS of 42.8 months in the 36 evaluable patients who had complete or partial response to NBTXR3 in the injected lesion (81.8%), compared to an mOS of 18.1 months observed in All Patients Treated (n=56), and 23.1 months in the total evaluable population (n=44), respectively. In addition, a positive correlation between Objective Response to RT-activated NBTXR3 in the injected lesion, Local Progression-Free Survival, and the extension of Overall Survival was observed.

These data suggest that the high rate of Objective Response to RT-activated NBTXR3 could potentially extend PFS and OS for elderly, frail patients with locally advanced head and neck cancer.

"With the Phase 1 study now complete, our focus is to ensure that we learn everything we can to anticipate the potential results of NANORAY-312. Of particular note were the data we observed regarding the positive correlation between Objective Response to NBTXR3 in the injected lesion, Local Progression Free Survival, Duration of Response in the injected lesion, and extension of Overall Survival," said Professor Christophe Le Tourneau, MD, PhD, principal investigator for Study 102 and co-principal investigator for NANORAY-312. *"Given the directional signals we observed in the exploratory analysis, the additional option to inject involved lymph nodes included in the design of the Phase 3, and the expected resemblance of the Phase 3 population to the evaluable population in the Phase 1, we see a strong opportunity to improve treatment outcomes for elderly patients with head and neck cancer in our ongoing registrational study."*

About NBTXR3

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 for which the product received a European CE mark in 2019. 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 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 NBTXR3 is being evaluated across multiple solid tumor indications as a single agent or in combination with anti-PD-1 immune checkpoint inhibitors, including in 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 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 NBTXR3 across tumor types and therapeutic combinations. In 2021, the Company announced an agreement with LianBio to expand development of NBTXR3 into Greater China and other Asian Markets, and in July 2023 Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

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, among other, Cambridge, Massachusetts (United States).

Nanobiotix is the owner of more than 20 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 certain “forward-looking” statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as “considers”, “envisages”, “believes”, “aim”, “continue”, “could”, “drive”, “enable”, “expect”, “further”, “look forward”, “may”, “ongoing”, “potential”, “promise”, “realize”, “subject to”, “success-based”, “up to”, “will”, and “would” or the negative of these and similar expressions. These forward-looking statements, which are based on the management’s current expectations and assumptions and on information currently available to management, include statements about the overall development of NBTXR3, including the timing and progress of clinical trials including uncertainties as to the timing of NANORAY-312 interim analysis; the extent to which the results from the clinical trial, including the study discussed in this press release, may be replicated in other studies and/or lead to advancement of product candidates to regulatory approval; the development of NBTXR3 pursuant to the license agreement with Janssen (the “Agreement”) and the potential payments for which Nanobiotix is eligible under the Agreement; and the financial position of Nanobiotix. Such forward-looking statements are made in light of information currently available to us and based on assumptions that Nanobiotix considers to be reasonable. However, these forward-looking statements are subject to numerous risks and uncertainties; the risks arising from Nanobiotix’s reliance on Janssen to conduct development and commercialization activities with respect to NBTXR3, including the potential for disagreements or disputes under the Agreement; the risk that Janssen may exercise its discretion in a manner that limits the resources contributed toward the development of NBTXR3 under the Agreement or may exercise its faculty to terminate without cause the Agreement; the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data; and the risk that the Company may not be able to secure additional capital on attractive terms, if at all. Furthermore, many other important risks factors and uncertainties, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 24, 2023 under “Item 3.D. Risk Factors” those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers – the AMF) on April 24, 2023 and those set forth in the half-year report filed with SEC on form 6-K and with AMF on September 26, 2023 (copies of which are available on www.nanobiotix.com), may adversely affect such forward-looking statements and cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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Attachment

- [2023-10-23 -- NTB -- Updated Data @ ESMO -- FINAL](#)