NANOBIOTIX Announces Completion of Phase 1 Study of NBTXR3 (JNJ-1900) in Pancreatic Cancer

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- **Investigators concluded that the encouraging oncologic outcomes coupled with a favorable safety profile warrant further evaluation in a randomized trial**
- **23 months median Overall Survival from date of diagnosis was observed in 22 patients with locally advanced or borderline resectable pancreatic cancer**
- **US FDA approved protocol amendment to launch new cohort evaluating RT-activated NBTXR3 combined with standard-of-care concurrent chemotherapy and recruitment is ongoing**
- **Full data from the completed dose escalation and dose expansion cohorts to be presented at a medical congress in 1H 2025**

PARIS and CAMBRIDGE, Mass., Dec. 09, 2024 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO — NASDAQ: NBTX – the " **Company**"), a late-clinical stage biotechnology company pioneering nanoparticle-based therapeutic approaches to expand treatment possibilities for patients with cancer and other major diseases, today announced the completion of the dose escalation and dose expansion parts of a Phase 1 study evaluating radiotherapy("RT")-activated NBTXR3 (JNJ-1900) for patients with locally advanced pancreatic cancer ("LAPC") or borderline resectable pancreatic cancer ("BRPC"). The Phase 1 study is being conducted by The University of Texas MD Anderson Cancer Center ("MD Anderson").

Patients with LAPC or BRPC often receive initial treatment with cytotoxic chemotherapy followed by RT +/- concurrent or maintenance chemotherapy.

This Phase 1 study was designed to evaluate the safety, feasibility, and early signs of efficacy of RT-activated NBTXR3 for patients with LAPC or BRPC after initial treatment with cytotoxic chemotherapy, in comparison to the historical data in patients who received RT +/- concurrent or maintenance chemotherapy after initial treatment with cytotoxic chemotherapy.

Investigators observed an mOS of 23 months from the date of diagnosis in 22 patients (20 with LAPC and 2 with BRPC) on the trial that compared favorably with outcomes at MD Anderson where the historical control for mOS in 144 patients treated at the same center was 19.2 months. Investigators concluded that RT-activated NBTXR3 was well tolerated by all patients and that the encouraging oncologic outcomes observed warrant further evaluation in a randomized trial.

Following these encouraging results from the study, MD Anderson submitted and received US FDA clearance for a new, additional study cohort evaluating the combination of NBTXR3 and standard-of-care concurrent chemoradiation. The new cohort has launched, and recruitment is ongoing.

"The results we have observed in this Phase 1 study give us confidence that NBTXR3 could have a significant impact for these patients," said Louis Kayitalire, MD, Chief Medical Officer at Nanobiotix. "We look forward to the data from the new cohort and believe the combination of NBTXR3 and concurrent chemoradiation could produce even more favorable outcomes for patients with locally advanced or borderline resectable pancreatic cancer."

Nanobiotix expects full results from the completed dose escalation and dose expansion parts of the study to be presented by MD Anderson at a medical congress in 1H 2025.

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 2023, Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

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 24, 2024 under "Item 3.D. Risk Factors", in Nanobiotix's 2023 universal registration document filed with the AMF on April 24, 2024, in Nanobiotix' 2024 semi-annual report under the caption "Supplemental Risk Factor" filed with the SEC on Form 6-K and with AMF on September 18 2024, 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

- 2024-12-09 -- NBTX -- Completes Ph1 NBTXR3 in Pancreatic Cancer -- FINAL