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EXPANDING LIFE

NANOBIOTIX Reports Updated Phase 1 Anti-PD-1 Combination Data That May Support the Immune Stimulation Potential of Radioenhancer NBTXR3 at the 37th Annual Meeting of the Society for Immunotherapy of Cancer

November 10, 2022

Data to be discussed during Nanobiotix Q3 Earnings Call at 8:00AM EST

- Data show that radiotherapy-activated NBTXR3 followed by anti-PD-1 was feasible and well tolerated in the complete dose escalation part of the Company's phase 1 immunotherapy study with a recommended phase 2 dose established at 33% of gross tumor volume in all 3 cohorts
- Results include 5 additional patients of 21 evaluable as of the data cutoff on 22 August 2022 and continue to suggest local control and immune stimulation regardless of prior anti-PD-1 exposure
- Objective reduction from baseline in all target lesions ("objective reduction") was observed in 71.43% of evaluable patients (15/21) and objective reduction of more than 30% was observed in 42.86% of evaluable patients (9/21)
- Objective reduction was observed in 66.66% of evaluable patients with cancer resistant to anti-PD-1 (10/15)
- As of the cutoff, systemic disease control was durable and had sustained for more than 6 months in 38.10% of evaluable patients (8/21)

PARIS and CAMBRIDGE, Mass., Nov. 10, 2022 (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 the Company's phase 1 immunotherapy study, Study 1100. These data will be presented during the 37th Annual Meeting of the Society for Immunotherapy of Cancer (“SITC”).

“Immune checkpoint inhibitors such as anti-PD-1 are the backbone of cancer immunotherapy and expanding the benefits of these therapies to more patients by improving response rates is one of the most urgent challenges facing the oncology community today,” said Jared Weiss, MD, Professor, Medicine-Oncology at the University of North Carolina Lineberger Comprehensive Cancer Center, and member of the Nanobiotix Scientific Advisory Board. *“Novel combinations that can help to stimulate an immune response and overcome or circumvent resistance to immune checkpoint inhibitors could provide the key to unlocking the full potential of these life-saving therapeutics for larger groups of patients. I am encouraged by the early data we have reported on NBTXR3 plus anti-PD-1 both for patients naïve to prior anti-PD-1 therapy and for those whose cancer was resistant to anti-PD-1 and look forward to further evaluation of the radioenhancer for patients with recurrent and/or metastatic cancers.”*

NBTXR3 Activated By Radiotherapy In Combination With Nivolumab Or Pembrolizumab In Patients With Advanced Cancers: Results From An Ongoing Dose Escalation Phase I Trial — Abstract #684

Summary of Updated Data

Reported data included 28 patients, with 21 evaluable for early signs of efficacy at the data cutoff on 22 August 2022. Treatment remained feasible and well-tolerated, with a safety profile consistent with expectations from stereotactic body radiation therapy (“SBRT”; “RT”) followed by anti-PD-1 immune checkpoint inhibitors.

Objective reduction from baseline in target lesions (“objective reduction”) was observed in 71.43% of evaluable patients (15/21). 42.86% of evaluable patients (9/21) showed objective reduction greater than 30%. 71.43% of evaluable patients (15/21) had cancer resistant to prior anti-PD-1 exposure and tumor regression was observed in 66.66% of these patients (10/15).

As of the data cutoff, systemic disease control was durable and had sustained for more than 6 months in 38.10% of evaluable patients (8/21). Delayed objective reduction has been observed in several patients, suggesting the potential for anti-cancer immune activity over time.

The recommended phase 2 dose (“RP2D”) of RT-activated NBTXR3 followed by anti-PD-1 was established at 33% of gross tumor volume in all 3 cohorts at the completion of the Study 1100 dose escalation part. The dose expansion part of the study is ongoing in the United States (“US”), with a protocol amended for robust evaluation of RT-activated NBTXR3 plus anti-PD-1 in patients with locoregional recurrent (“LRR”) or recurrent and/or metastatic (“R/M”) head and neck squamous cell carcinoma (“HNSCC”) that is either naïve or resistant to prior anti-PD-1 exposure.

The Company plans to submit a registrational phase 3 protocol for the evaluation of RT-activated NBTXR3 plus anti-PD-1 in patients with LRR or R/M HNSCC resistant to anti-PD-1 to the US Food and Drug Administration in the first quarter of 2023.

Conference Call Information

The updated data to be presented at SITC will be discussed during a conference call and live audio webcast on Thursday, November 10, 2022, at 8:00 AM ET / 2:00 PM CET.

The live webcast of the call may be accessed by visiting the investors section of the company's website at www.nanobiotix.com. Participants may register for the call [here](#). They will be able to join the call via dial-in or one-click dial-out. The Company recommends that participants join 10 minutes

prior to the start of the call.

A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the company's website.

About Study 1100

Study 1100 is a phase 1, multicenter, dose escalation and dose expansion study in the United States. The complete dose escalation part included three cohorts: (i) locoregional recurrent (LRR) or R/M HNSCC amenable to reirradiation of the head and neck; (ii) lung metastases from any primary cancer eligible for anti-PD-1; (iii) liver metastases from any primary cancer eligible for anti-PD-1. Patients received a single intratumoral injection of NBTXR3 prior to their first session of stereotactic body radiation therapy (SBRT). Patients were treated with pembrolizumab (Keytruda®) or nivolumab (Opdivo®) after completion of SBRT. A recommended phase 2 dose for all three cohorts was established at 33% of gross tumor volume.

The dose expansion part of Study 1100 is now ongoing with a protocol amended for robust evaluation of NBTXR3 plus anti-PD-1 in patients with LRR or R/M HNSCC that is either naïve to prior anti-PD-1 exposure or resistant to prior anti-PD-1 exposure. The protocol includes three amended cohorts: (i) LRR or R/M HNSCC amenable to reirradiation that is resistant to prior anti-PD-1 exposure; (ii) LRR or R/M HNSCC amenable to reirradiation that is naïve to prior anti-PD-1 exposure; and (iii) non-small cell lung cancer, malignant melanoma, hepatocellular carcinoma, renal cell carcinoma, urothelial cancer, cervical cancer, triple-negative breast cancer that has metastasized to soft tissues, lung metastases, or liver metastases that is resistant to prior anti-PD-1 exposure.

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. 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.

NBTXR3 is being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) as the primary development pathway. The company-sponsored phase I dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy; and a phase III global registrational study was launched in 2021. 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 III study.

Nanobiotix has also prioritized an Immuno-Oncology development program—beginning with a Company-sponsored phase I clinical study evaluating NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors for patients with locoregional recurrent or recurrent/metastatic HNSCC, or lung or liver metastases from any primary cancer eligible for anti-PD-1 therapy.

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in a strategic collaboration strategy with world class partners 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 I and phase II studies to evaluate NBTXR3 across tumor types and therapeutic combinations.

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. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, and Germany. Nanobiotix has been listed on Euronext: Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 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. The company's resources are primarily devoted to the development of its lead product candidate—NBTXR3—which is the product of its proprietary oncology platform and has already achieved market authorization in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®.

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 "at this time," "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designated to," "may," "might," "on track," "plan," "potential," "predict," "objective," "shall," "should," "scheduled," and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, include statements about the timing and progress of clinical trials, the timing of our presentation of data, the results of our preclinical and clinical studies and their potential implications. 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, including with respect to the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data notwithstanding positive early clinical results; the risks associated with the evolving nature of the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to it; the risk that the EIB may accelerate the loans under finance contract and its amendment upon the occurrence of customary events of default; the risk that Company may not be able to secure additional capital on attractive terms, if at all; the risk that Company may not be able to expand its product pipeline by developing NBTXR3 in additional indications, including in combination with I-O treatment;. 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 8, 2022 under "Item 3.D. Risk Factors" and 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 8, 2022, (a copy of which is available on www.nanobiotix.com), as well as those set forth in the half-year financial report filed with the AMF on September 28, 2022, 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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