NANOBIOTIX Provides Third Quarter 2024 Update and Progress on Nanotherapeutics Platforms

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- Transferred US sponsorship of global Phase 3 NANORAY-312 head and neck cancer study, a key step in the preparation for potential NBTXR3 regulatory submission
- Added expert industry leaders to Supervisory Board, further strengthening support for the Company's long-term growth strategy
- NBTXR3 program update from pancreatic cancer study and lung cancer study with MD Anderson expected 4Q 2024 and 1H 2025, respectively
- Update on expansion of product portfolio to include disruptive nanotherapeutic platform Curadigm expected 4Q 2024
- €53.2 million in cash and cash equivalents as of September 30, 2024 with cash runway into 4Q 2025

PARIS and CAMBRIDGE, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO - NASDAQ: NBTX - the **"Company")**, a late-clinical stage biotechnology company pioneering nanoparticle-based approaches to expand treatment possibilities for patients with cancer and other major diseases, provided an update on operational progress and reported financial results for the third quarter of 2024.

"Our strong momentum continues as we further execute across initiatives designed to advance our potentially first-in-class nanoparticle-based therapeutic platforms for millions of patients worldwide. In the NBTXR3 program, we began sponsorship transfer of our global, pivotal NANORAY-312, which is a key step for the potential regulatory submission of NBTXR3 and the promise of our lead candidate to help address the unmet needs of 12 million patients with solid tumors globally who receive radiotherapy each year," said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. "We were also pleased to expand our Supervisory Board to include leading experts in both the scientific and financial communities to help foster sustainable long-term growth across our platforms. In the fourth quarter, we expect updated dose escalation data for NBTXR3 in pancreatic cancer from our MD Anderson collaboration, as well as an update to our Curadigm program, which is the next-wave of nanoparticle-based platforms from Nanobiotix."

Third Quarter 2024 Operational Highlights

In an important step forward for the potential NBTXR3 regulatory pathway, Nanobiotix and Janssen Pharmaceutica NV, a Johnson & Johnson Company ("Janssen"), have initiated the planned sponsorship transfer of NANORAY-312, a global Phase 3 study evaluating radiotherapy-activated NBTXR3 for patients with head and neck cancer ineligible for cisplatin, from Nanobiotix to Janssen. Nanobiotix has transferred the sponsorship of the study in the United States to Janssen as planned. The process of transferring the remaining global regions is ongoing. Nanobiotix estimates this process will require several quarters to complete. Janssen is the global licensee for NBTXR3 co-development and commercialization. Accountability for the NANORAY-312 sponsorship will enable the licensee to submit NBTXR3 for global registration in the event of positive trial results.

The Company strengthened its Supervisory Board with the nominations of Dr. Margaret A. Liu and Ms. Anat Naschitz as board observers, two key additions intended to further equip the Company for sustainable long-term growth. Dr. Liu brings a wealth of experience in US and international academia, pharmaceuticals, biotechnology and public policy, and Ms. Naschitz brings world-class expertise in raising and deploying capital to support disruptive innovation for the benefit of patients, healthcare professionals and investors.

Upcoming Milestones

Janssen License Agreement

- **Locally Advanced Head and Neck Squamous Cell Carcinoma (LA-HNSCC):** Nanobiotix continues to expect the interim analysis for NANORAY-312 after the required number of events and last patient recruited in 1H 2026

MD Anderson Collaboration

- **Pancreatic Cancer:** Updated Phase 1b dose escalation data expected 4Q 2024
- **NSCLC:** Initial Phase 1 dose escalation data in inoperable, recurrent NSCLC amenable to re-irradiation expected 1H 2025
- **Esophageal Cancer:** Presentation of first Phase 1b/2 data expected in 2025

Preclinical Nanoparticle-Based Platforms

- **Curadigm Nanoprimer:** Program update on the disruptive potential of Curadigm and the platform's opportunity to redefine the discovery and design of next-gen therapies expected 4Q 2024

Third Quarter Financial Updates

Nanobiotix reported cash and cash equivalents of €53.2 million (unaudited) as of September 30, 2024.

Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €53.2 million as of September 30, 2024 to fund operations into Q4 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 patent families 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 our 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

- 2024-11-12 -- NBTX -- 3Q24 Financial Results -- FINAL