Nanobiotix Announces Protocol Amendment to Ongoing Global Phase 3 Head and Neck Cancer Study

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PARIS and CAMBRIDGE, Mass., May 04, 2026 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO — NASDAQ: NBTX – the " **Company**"), a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer and other major diseases, today announced FDA acceptance of a protocol amendment to the ongoing pivotal NANORAY-312 study.

This protocol amendment, submitted by NANORAY-312 global sponsor Johnson & Johnson, eliminates the previously planned interim analysis and modifies the final analysis to include fewer events than originally planned and to be conducted sooner.

In Nanobiotix's view, this decision could accelerate and expand the global registration pathway for JNJ-1900 (NBTXR3) in head and neck cancer, providing the opportunity for earlier increased revenue generation for the Company.

Nanobiotix anticipates that the modified final analysis should readout in the same timeframe as the previously planned interim analysis. Exact timing will depend on when clinical events occur.

Per the license agreement, Nanobiotix is eligible to receive hundreds of millions in aggregate payments in the next few years, subject to the achievement of remaining development and regulatory milestone events related to the first two programs evaluating JNJ-1900 (NBTXR3) in head and neck cancer and lung cancer.

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 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 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 subsidiary in Cambridge, Massachusetts (United States).

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

Cautionary Statement

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 advancement, timing of clinical trial data including, if any, analysis readouts and submission of regulatory filings in respect of NANORAY-312 and lung cancer, and the financial outcomes of the Janssen license Agreement. Words such as "anticipates," "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 milestone payments potentially due to the Company in respect of clinical trials are not reached at all or are affected by further timing changes controlled by Johnson & Johnson , as the sponsor of such trials. 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 March 31, 2026 under "Item 3.D. Risk Factors", in Nanobiotix's 2025 universal registration document filed with the AMF on March 31, 2026 under "chapter 1.5 Risk Factors", and subsequent filings Nanobiotix makes with the SEC and AMF from time to time, which are available on the SEC's website at www.sec.gov and on the AMF's website at www.amf.org, 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

- 2026-05-04 -- NBTX -- Protocol Amendment for Ph3 NANORAY-312 Trial -- FINAL