NANOBIOTIX Announces US FDA Protocol Acceptance for New Randomized Phase 2 Study Evaluating NBTXR3 for Patients with Stage Three Lung Cancer

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PARIS and CAMBRIDGE, Mass., May 14, 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 that the U.S. Food and Drug Administration ("US FDA") issued a Study May Proceed Letter for a randomized Phase 2 study evaluating NBTXR3 for the treatment of patients with stage 3, unresectable non-small cell lung cancer ("NSCLC"). An IND to support this trial was submitted by the global trial sponsor, Johnson & Johnson Enterprise Innovation Inc., a Johnson & Johnson company.

"The NBTXR3 collaboration established by our global licensing agreement with Janssen Pharmaceutica NV continues to make progress toward our goal of reaching millions of patients with cancer around the world. The US FDA acceptance of the protocol for this new Phase 2 study has the potential to expand the NBTXR3 development pipeline to a new indication where innovation could potentially provide important outcomes," said Louis Kayitalire, MD, chief medical officer at Nanobiotix. "We look forward to continuing to prepare for the launch of the 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 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, among other, Cambridge, Massachusetts (United States).

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, 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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Attachments

- 2024-05-14 -- NBTX -- FDA Accepts Ph2 NBTR3 Study Protocol -- FINAL.pdf