NANOBIOTIX Announces First Patient Injected in New Phase 1/2 Study Evaluating Radiotherapy-Activated NBTXR3 Plus Anti-PD-1 for Patients With Advanced Cancers

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PARIS and CAMBRIDGE, Mass., July 19, 2023 (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 that the first patient has been injected in a Phase 1/2 study evaluating NBTXR3 activated by radiation therapy in combination with anti-PD-1/L-1 immune checkpoint inhibitors for the treatment of patients with advanced solid tumor malignancies that have spread to lungs (lung metastases) and/or liver (liver metastases). The trial (NCT05039632) is being conducted as part of an ongoing strategic collaboration between Nanobiotix and The University of Texas MD Anderson Cancer Center evaluating radiotherapy-activated NBTXR3 across solid tumor indications and treatment combinations.

"Fundamental in the effort to bring the potential benefits of NBTXR3 to millions of patients around the world is an expansive development program that pushes the scientific boundaries of oncology," said Leonard A. Farber, MD, Chief Clinical and Medical Affairs Officer at Nanobiotix. "This collaboration expands development of NBTXR3 across solid tumor indications, therapeutic combinations, and treatment modalities in parallel with studies led by Nanobiotix. We are pleased with the momentum we continue to build in our program and look forward to the opportunity to bring NBTXR3 to more patients."

This new study expands the ongoing strategic collaboration to five actively recruiting trials. Beyond the new study, the additional active studies in the collaboration include:

- A Phase 2 study of radiotherapy-activated NBTXR3 in combination with anti-PD-1 for patients with recurrent or metastatic head and neck cancer (NCT04862455)
- A Phase 1 study of radiotherapy-activated NBTXR3 for patients with inoperable non-small cell lung cancer (NCT04505267)
- A Phase 1 study of radiotherapy-activated NBTXR3 for patients with pancreatic cancer (NCT04484909)
- A Phase 1 study of NBTXR3 activated by radiotherapy in combination with chemotherapy for patients with esophageal cancer (NCT04615013)

Nanobiotix expects data from the collaboration to be presented in H2 2023.

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 1 dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy; and a Phase 3 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 3 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 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 II studies to evaluate NBTXR3 across tumor types and therapeutic combinations. In 2021, the Company announced an agreement with LianBio to expand development of NBTXR3 into Greater China and other Asian Markets, and 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. 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 20 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.

Cautionary Statement

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 "additional", "aim", "continue", "could", "drive", "enable", "expect", "further", "look forward", "may", "ongoing", "potential", "promise", "realize", "subject to", "success-based", "up to", "will", and "would" 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 overall development of NBTXR3, including the timing and progress of clinical trials; the development of NBTXR3 pursuant to the license, agreement with Janssen (the "Agreement") and the potential payments for which Nanobiotix is eligible under the Agreement; the potential for, and possible size of, the proposed equity investment by JJDC; and the financial position of Nanobiotix. 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 conditions to closing, including necessary regulatory approvals, are not satisfied in a timely manner or at all; the risks arising from Nanobiotix's reliance on Janssen to conduct development and commercialization activities with respect to NBTXR3, including the potential for disagreements or disputes under the Agreement; the risk that Janssen may exercise its discretion in a manner that limits the resources contributed toward the development of NBTXR3 under the Agreement or may exercise its faculty to terminate without cause the Agreement; the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data; and the risk that the Company may not be able to secure additional capital on attractive terms, if at all. 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 24, 2023 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 24,2023, (copies of which are available on www.nanobiotix.com), 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.

Contacts

Nanobiotix

Communications Department
Brandon Owens
VP, Communications
+1 (617) 852-4835
contact@nanobiotix.com

Investor Relations Department
Craig West
SVP, Investor Relations
+1 (617) 583-0211
investors@nanobiotix.com

Media Relations

FR – **Ulysse Communication**
Pierre-Louis Germain
+ 33 (0) 6 64 79 97 51
plgermain@ulysse-communication.com

Global – **LifeSci Advisors**
Ligia Vela-Reid
+44 (0) 7413825310
Lvela-reid@lifesciadvisors.com

Attachment

- 2023-07-19 -- NBTX -- FPI in Ph1-2 NBTXR3 in Advanced Solid Cancers -- FINAL