NANOBIOTIX Announces Regulatory Harmonization and New Composition of Matter Patent Filed for JNJ-1900 (NBTXR3)

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- Health authorities in major European countries have accepted the reclassification of JNJ-1900 (NBTXR3) from a medical device to a medicinal product, aligning with regulatory status in the US and other major markets
- Medicinal product classification supports unified global regulatory classification, facilitating future global strategies and filings
- New composition of matter patent for JNJ-1900 (NBTXR3) filed by Nanobitotix

PARIS and CAMBRIDGE, Mass., July 07, 2025 (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, today announced two important developments that aim to reinforce the global positioning of potential first-in-class radioenhancer JNJ-1900 (NBTXR3), which is licensed by Janssen Pharmaceutica NV, a Johnson & Johnson company.

Health authorities in major European countries have agreed to formally reclassify JNJ-1900 (NBTXR3) from a medical device to a drug, completing a process initiated by Johnson & Johnson to harmonize the product candidate's regulatory status with classifications already in place in the United States and other major markets. The reclassification follows updated insights into the product candidate's mechanism of action.

In parallel, Nanobiotix has filed a new composition of matter patent for JNJ-1900 (NBTXR3) that aims to reinforce the intellectual property foundation supporting the product candidate.

"These updates reflect our continued commitment to the JNJ-1900 (NBTXR3) program," said Laurent Levy, co-founder and chairman of the executive board at Nanobiotix. "We are pleased with the progress achieved with health authorities and proud to continue advancing this potential first-in-class product candidate toward patients in need."

JNJ-1900 (NBTXR3) is currently the subject of a comprehensive global clinical development program across multiple tumor types and therapeutic combinations, including a pivotal Phase 3 trial in head and neck 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 subsidiaries in Cambridge, Massachusetts (United States) amongst other locations.

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

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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 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 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 02, 2025 under "Item 3.D. Risk Factors", in Nanobiotix's 2024 universal registration document filed with the AMF on April 02, 2025,, 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

- 2025-07-07 -- NTBX -- Composition of Matter Patent for NBTXR3 -- FINAL