



NANOBIOTIX Announces First Patient Enrolled in NANORAY-312 Global Phase III Registrational Study of NBTXR3 in Head and Neck Cancer

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- **First patient randomized in pivotal phase III study evaluating radiotherapy-activated NBTXR3 with or without cetuximab in high-risk elderly patients with locally advanced head and neck squamous cell carcinoma**
- **The randomized study is designed to demonstrate treatment outcome superiority of radiotherapy-activated NBTXR3 versus the standard of care for global registration**
- **The US Food and Drug Administration granted Fast Track designation for investigation of NBTXR3 in this patient population, providing the opportunity for priority review and accelerated approval**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 5, 2022-- Regulatory News:

[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 that the first patient has been enrolled in NANORAY-312, a global, open-label, two-arm, randomized, Investigator’s Choice phase III registration study that is designed to investigate the efficacy and safety of radiotherapy-activated NBTXR3 with or without cetuximab versus radiotherapy with or without cetuximab in high-risk, chemotherapy-ineligible elderly patients with locally-advanced head and neck squamous cell carcinoma (LA-HNSCC). The study is co-led by principal investigators Sue Yom, MD, PhD, Professor and Vice Chair, Strategic Advisory Department of Radiation Oncology; Professor, Otolaryngology-Head and Neck Surgery at The University of California, San Francisco, and Christophe Le Tourneau, MD, PhD, senior medical oncologist and head of the Department of Drug Development and Innovation (D3i) at Institut Curie (Paris).

“Elderly patients with locally advanced head and neck cancer need new therapeutic options to improve treatment outcomes,” said Dr. Yom. “I look forward to working with patients and colleagues around the world through the NANORAY-312 study as we evaluate the opportunity for radiotherapy-activated NBTXR3 in this indication.”

Eligible participants for NANORAY-312 will be treated with NBTXR3 at a 1:1 ratio after an Investigator’s Choice of radiotherapy alone or radiotherapy in combination with cetuximab. NANORAY-312 aims to enroll 500 patients across sites in the United States, Europe, and Asia. To date, 128 sites have been qualified in 29 countries. The primary endpoint of the pivotal study is Progression-free Survival (PFS) and key secondary endpoints include Overall Survival (OS), response rates, and quality of life. Nanobiotix expects a futility analysis at 18 months and an interim readout 30 months after the first patient is randomized.

“Bringing potentially practice-changing innovation to the patients who need it most is the aim of the NANORAY-312 study,” said Professor Le Tourneau. “After leading the phase I study of NBTXR3 in locally advanced head neck cancer, I am encouraged by the opportunity to further evaluate the impact this new product candidate could have for elderly patients with this disease.”

NANORAY-312 builds on Nanobiotix Study 102, a phase I trial evaluating safety and early signs of efficacy for radiotherapy-activated NBTXR3 in high-risk elderly LA-HNSCC patients who are chemotherapy-ineligible and intolerant to cetuximab. Preliminary data presented at the 2021 Annual Meeting of the American Society for Radiation Oncology (ASTRO) showed that the treatment was feasible and well tolerated at all dose levels. Exploratory efficacy data showed a high target lesion objective response rate of 85.4% and a target lesion complete response rate of 63.4%, along with a median PFS of 10.6 months and median OS of 18.1 months in the evaluable patient population, which has a poorer prognosis than those patients eligible for the phase III study.

“The first patient enrolled in our global phase III study is a testament to the tireless commitment of our team, investigators, and strategic collaborators,” said Laurent Levy, co-founder and chairman of the executive board at Nanobiotix. “Together, we strive to bring innovation to patients with cancer and our belief is that NANORAY-312 will represent another critical step in making our vision a reality.”

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of radiotherapy-activated NBTXR3 in the NANORAY-312 population, which includes the opportunity for Priority Review and Accelerated Approval.

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 I dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy. 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.

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 and lung or liver metastases from any primary cancer eligible for anti-PD-1 therapy either naïve or resistant to prior PD-1 (either primary or secondary as per SITC criteria).

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in strategic collaborations with world class partners 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 I and phase II studies to evaluate NBTXR3 across tumor types and therapeutic combinations. In 2021, the Company entered into an additional strategic collaboration agreement with LianBio to support its global phase III study in Asia along with four future registrational studies.

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, Germany and Switzerland.

Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 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](#).

Disclaimer

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 "at this time," "anticipate," "believe," "expect," "intend," "on track," "plan," "scheduled," and "will," 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 timing and progress of clinical trials, the timing of our presentation of data, the results of our preclinical and clinical studies and their potential implications. 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 subsequent studies and ongoing or future clinical trials may not generate favorable data notwithstanding positive early clinical results and the risks associated with the evolving nature of the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to it. Furthermore, many other important factors, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 7, 2021 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 7, 2021, each as updated in our Half-Year Financial Report filed with the AMF and the SEC on September 8, 2021 (a copy of which is available on www.nanobiotix.com), as well as other known and unknown risks and uncertainties 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.



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