

NANOBIOTIX

EXPANDING LIFE

NANOBIOTIX Provides Corporate Update and Highlights Key 2022 Milestone Targets

January 10, 2022

- **Evaluation of NBTXR3 for global registration in priority head and neck cancer pathway proceeds with the first European patient randomized in global phase III NANORAY-312 study; US and Asia site activation expected in 2022**
- **Priority NBTXR3 plus anti-PD-1 combination program poised to advance as the Company seeks to define registration pathway with regulatory agencies based on initial data from ongoing phase I immunotherapy study**
- **Operating runway extended into second quarter 2023 as a result of enhancing operational efficiencies and optimizing capital allocation for continued investment in priority development pathways**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 10, 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 provided a corporate update highlighting key priorities and anticipated development milestones for 2022.

“We believe 2021 provided strong validation of the broad potential therapeutic benefit of NBTXR3 and the capabilities of the Nanobiotix team,” said Laurent Levy, co-founder and chairman of the executive board of Nanobiotix. “Not only did our single-agent and combination development programs yield new data suggesting radiotherapy-activated NBTXR3 may improve clinical outcomes for patients with either local or systemic disease, but we were also able to launch NANORAY-312, our global phase III registration study in head and neck cancer. This momentum enabled us to move quickly to begin 2022, with the first European patient randomized in our phase III study and recruitment efforts well under way. In parallel, in 2021 we strengthened our leadership team with the appointment of both a new supervisory board Chairman and new Chief Financial Officer; and added a new strategic partner to advance and expand development of NBTXR3 in Asia. Moreover, we took measures to increase operational efficiencies and optimize capital allocation, effectively extending our operating runway while further strengthening our priority development pathways. Our priorities for the year remain focused on executing our ongoing studies, capturing the opportunity to drive value by defining our registration strategy in immunotherapy, and expanding the tumor-agnostic, combination-agnostic profile of NBTXR3 through our strategic collaborations.”

2022 Corporate Priorities

The Nanobiotix mission is to improve treatment outcomes for patients around the world by developing and commercializing disruptive, nanophysics-based therapeutic solutions across multiple major disease areas, beginning with cancer. In 2022, Nanobiotix plans to continue to grow and strengthen its organizational capabilities in order to deliver on the potential of its lead product candidate, NBTXR3.

Key corporate priorities for the year are as follows:

- Focus Company-led development efforts on the execution of NANORAY-312, a global, pivotal study seeking regulatory market approval of NBTXR3 as a single-agent activated by radiation in locally advanced head and neck squamous cell carcinoma (HNSCC; head and neck cancer) and the advancement of a follow-on checkpoint inhibitor combination strategy for patients naïve to anti-PD-1 treatment as well as patients with inadequate or no response to prior anti-PD-1 treatment
- Advance the expansion of NBTXR3’s global pipeline through existing collaborations and/or the addition of new collaborations that can potentially contribute complementary development and/or commercial capabilities
- Further align resources and capital allocation with strategic priorities and enhance operating efficiencies
- Deepen operational expertise in key functional areas to support continued company growth
- Continue to foster a company culture of innovation, integrity, accountability, transparency, and inclusion

2022 Development Pipeline Objectives

In 2022, the Nanobiotix development program will continue to focus on: (i) Execution of Company-led priority pathways in HNSCC and immunotherapy, and (ii) working with existing and future collaborators to expand the development footprint for NBTXR3.

Key development objectives and expected milestones as follows:

- Advance toward NBTXR3 global commercial registration through NANORAY-312, evaluating the product candidate as a single-agent activated by radiotherapy for high-risk elderly patients with locally advanced HNSCC following preliminary survival data from phase I dose expansion study (Study 102 Expansion) showing a potential benefit for elderly patients with a worse prognosis. Expected 2022 milestones include:

- Randomize First NANORAY-312 Patient in Europe – January 2022 (Achieved)
- Activate First NANORAY-312 US Site
- Activate First NANORAY-312 Asia Site (LianBio)
- Establish a planned path to registration for NBTXR3 in combination with anti-PD-1 following initial data from the Company's ongoing phase I study (Study 1100) suggesting NBTXR3 may prime immune response, enhance response rates in anti-PD-1 naïve patients, and help overcome resistance to prior anti-PD-1 therapy in non-responders. Expected 2022 milestones include:
 - Establish Recommended Phase II Dose (RP2D) in all cohorts
 - Present Updated Study 1100 Data
 - Announce Development Next Steps Following Regulatory Agency Feedback
- Expand evaluation of NBTXR3 safety and feasibility to additional solid tumor indications and therapeutic combinations outside of Company-led pathways through collaborators. Expected 2022 milestones include:
 - Establish Recommended Phase II Dose (RP2D) in Pancreatic Cancer
 - Present Data from Phase I evaluation of NBTXR3 plus chemoradiation in HNSCC
 - Present Data from Phase I/II evaluation of NBTXR3 plus chemoradiation in Rectal Cancer

2021 Year-End Cash

As of December 31, 2021, Nanobiotix estimates that it had approximately €83.9 million in cash, cash equivalents, and investments, compared to €119.2 million as of December 31, 2020. Following comprehensive operational adjustments undertaken in the second half of 2021, Nanobiotix has been able to extend its operating runway and now expects that its cash, cash equivalents, and investments as of December 31, 2021, excluding any future potential milestones that may be received by the Company from collaborations, will enable the Company to fund its current operational plan into the second quarter of 2023. This estimate of cash, cash equivalents and investments is preliminary and is based on information currently available and may differ from the actual cash balance to be included in the Company's audited financial statements.

Upcoming Investor Conferences in January 2022

H.C. Wainwright Bioconnect Conference

Date: January 10-13, 2022

Format: Corporate presentation

Time: Presentation available for registered attendees starting January 10, 2022 at 7:00 AM (EST) / 1:00 PM (CET)

Biotech Showcase™ 2022

Date: January 17-19, 2022

Format: Corporate presentation and virtual one-on-one meetings with investors

Time: Presentation available for registered attendees starting January 10, 2022 at 7:00 AM (EST) / 1:00 PM (CET)

An updated corporate overview presentation is available on the Investors section of the Company's website at <https://www.nanobiotix.com/stock-information> and a webcast of the H.C. Wainwright Bioconnect Conference will be archived in the events section at <https://www.nanobiotix.com/events>.

2022 Financial Agenda

- March 30, 2022 – 2021 Full-Year Corporate and Financial Update
- May 10, 2022 – First Quarter 2022 Corporate and Financial Update
- June 17, 2022 – Annual General Meeting, Paris, France
- September 7, 2022 – 2022 Half-Year Corporate and Financial Update
- November 9, 2022 – Third Quarter 2022 Corporate and Financial Update

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 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 NANBIOTIX

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.

2022 Development Outlook Overview

STUDY	STATUS	ANTICIPATED 2022 MILESTONES
Company-Led Single-Agent Pathway		
Phase III Registration Study of NBTXR3 in Head and Neck Cancer	First patient randomized in Europe	Expect site activation in US
Nanobiotix Study NANORAY-312		Expect site activation in Asia (LianBio)
Phase I Expansion Study of NBTXR3 in Head and Neck Cancer	Survival data presented at ASTRO 2021	Continued follow up of patients to assess longer term safety and efficacy data
Nanobiotix Study 102 Expansion		
Post-Registrational Study of NBTXR3 in Soft Tissue Sarcoma	In preparation	Preparation for study launch in EU

Company-led Checkpoint Inhibitor Combination Pathway

Phase I Study of NBTXR3 in Combination with Anti-PD-1 for Patients with Head and Neck Cancer, Lung Metastasis and/or Liver Metastasis	Updated results presented at ASTRO 2021	Expect determination of RP2D for all cohorts
Nanobiotix Study 1100	Contact initiated with regulatory agencies regarding development plan in IO	Expect presentation of updated data
		Expect announcement of development next steps in IO following regulatory agency feedback

Collaborator-led Expansion Across Indications and Therapeutic Combinations

Phase II Study of NBTXR3 in Combination with Anti-PD-1 for Patients with Recurrent/Metastatic Head and Neck Cancer with Limited PD-L1 Expression	First patients enrolled in 2021	Updates to be provided as they are made available by MD Anderson
MD Anderson Study 2020-0541	Active and recruiting	
Phase II Study of NBTXR3 in Combination with Anti-PD-1/L1 for Patients with Inoperable Head and Neck Cancer Amenable to Re-irradiation	Active and recruiting	Updates to be provided as they are made available by MD Anderson
MD Anderson Study 2020-0354		
Phase I Study of NBTXR3 in Esophageal Cancer	Active and recruiting	Updates to be provided as they are made available by MD Anderson
MD Anderson Study 2020-0122		
Phase I Study of NBTXR3 in Pancreatic Cancer	Active and recruiting	Expect determination of RP2D
MD Anderson Study 2019-1001	First dose level completed Final dose level enrolling	Updates to be provided as they are made available by MD Anderson
Phase I Study of NBTXR3 in Lung Cancer Amenable to Re-irradiation	Active and recruiting	Updates to be provided as they are made available by MD Anderson
MD Anderson Study 2020-0123		
Phase I/II Study of PEP503 (NBTXR3) with Radiotherapy in Combination with Concurrent Chemotherapy for Patients with Head and Neck Cancer	Concluded	Expect data presentation
Study PEP503-HN-1002		
Phase I/II Study of PEP503 with Radiotherapy in Combination with Concurrent Chemotherapy for Patients with Locally Advanced or Unresectable Rectal Cancer	Concluded	Expect data presentation

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