
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

Date of Report: June 4, 2021

Commission File Number: 001-39777

Nanobiotix S.A.
(Exact Name of Registrant as Specified in its Charter)

60 Rue de Wattignies
75012 Paris, France
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXHIBIT INDEX

Exhibit Title

[99.1](#) Press Release, dated June 3, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NANOBIOTIX S.A.
(Registrant)

June 4, 2021

By: /s/ Philippe Mauberna
Philippe Mauberna
Chief Financial Officer

PRESS RELEASE

NANOBIOTIX REPORTS NEW DATA FOR POTENTIAL FIRST-IN-CLASS RADIOENHANCER NBTXR3 IN COMBINATION WITH ANTI-PD-1 SHOWING LOCAL OR DISTANT TUMOR REGRESSION IN 76.9% OF EVALUABLE PATIENTS REGARDLESS OF PRIOR ANTI-PD-1 EXPOSURE

Data to be Presented at the 2021 Annual Meeting of the American Society for Clinical Oncology

- Results show NBTXR3 plus radiotherapy could potentially stimulate immune response and convert anti-PD-1 non-responders into responders
- Objective response was observed in 60% of anti-PD-1 naïve patients and 50% of prior non-responders
- Data suggest abscopal effect in some patients (i.e., reduction in non-injected / non-irradiated lesions)
- To date, the overall adverse event profile for the 16 injected patients has not differed from what is expected with radiotherapy or anti-PD-1 agents (head and neck cancer and non-small cell lung cancer primary tumors)
- New readout could provide promising signals for NBTXR3 as a potential pillar of immunotherapy
- Following ASCO, Nanobiotix will host an investor event on Friday, June 11, 2021 at 8:00 am Eastern Time (14:00 Central European Time), to provide an in-depth review of the immunotherapy data with several key opinion leaders including study investigators (Register [here](#))

Paris, France; Cambridge, Massachusetts (USA); June 3, 2021 - **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 the upcoming presentation of updated data from the Company’s immunotherapy development pathway at the 2021 Annual Meeting of the American Society for Clinical Oncology (ASCO).

Cancer immunotherapies such as anti-PD-1 have shown promising clinical outcomes over the past two decades and are often used to treat advanced cancers once other therapies have reached the end of their effectiveness. However, across tumor indications, the significant majority of patients (80-85% according to published data) receive only a temporary benefit—or no benefit at all—from anti-PD-1, as they either develop resistance to the therapy over time or are non-responsive to treatment altogether.

“Improving response rates to immune checkpoint inhibitors is currently a key challenge for the medical and scientific community,” said Tanguy Seiwert, MD, director of the head and neck oncology disease group at Johns Hopkins Medicine. “The data we have seen to date suggest that NBTXR3 could bring a completely different local and systemic approach to overcoming this barrier in immunotherapy.”

Given early data showing immune activity triggered by the physical mechanism of action of radiotherapy-activated NBTXR3, Nanobiotix aims to address the significant unmet need in cancer immunotherapy by combining NBTXR3 plus radiotherapy with anti-PD-1 in advanced cancers to potentially improve treatment outcomes for patients regardless of their prior exposure to immune checkpoint inhibitors.

“Changing the practice of immunotherapy is a challenge requiring innovation that can address unmet needs in the first-line for patients with primary resistance and in later lines for secondary resistance,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. “While our overall strategy is to develop NBTXR3 as a solid tumor-agnostic, therapeutic combination-agnostic agent, this particular study is designed to address both challenges by evaluating NBTXR3 plus radiotherapy in combination with anti-PD-1 across advanced cancer indications for both anti-PD-1 naïve patients and prior non-responders. The update we will present at ASCO adds to our growing body of data regarding our radioenhancer as a potential primer of immune response that could combine with anti-PD-1 and other checkpoint inhibitors to improve treatment outcomes for millions of patients.”

Priming Immune Response and Immunotherapy Combination in Advanced Cancers

Abstract #2590: A Phase I Study of NBTXR3 Activated by Radiotherapy for Patients with Advanced Cancers Treated with an Anti-PD-1 Therapy

Background

The Nanobiotix phase I study of NBTXR3 activated by radiotherapy for patients with advanced cancers treated with an anti-PD-1 therapy (Study 1100), is a multicenter, open-label, non-randomized phase I dose escalation with dose expansion study to establish the recommended phase II dose (RP2D) of NBTXR3 plus radiotherapy in combination with anti-PD-1 in three (3) cohorts: (i) inoperable locoregional recurrent or recurrent and metastatic head and neck cancer (R/M head and neck squamous cell carcinoma; R/M HNSCC); (ii) lung metastasis; (iii) liver metastasis. The study is being administered in the United States.

The secondary endpoints are objective response rate (ORR), safety and feasibility, and body kinetic profile.

Updated Results

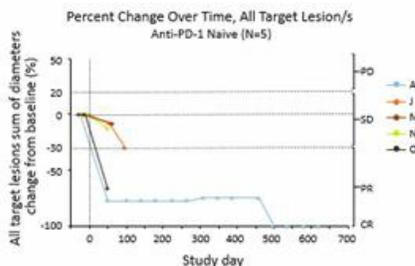
Safety

NBTXR3 administration by intratumoral injection was feasible and well-tolerated. To date, the overall adverse event (AE) profile has not differed from what is expected with radiotherapy or anti-PD-1 agents. 16 serious AEs were observed, of which four (4) were identified as NBTXR3 or injection related.

Efficacy

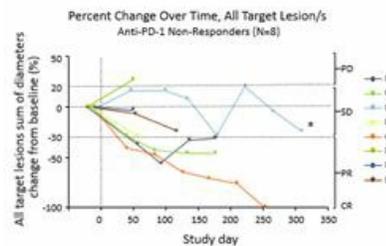
As of the data cut-off, 16 patients in the study received NBTXR3 plus radiotherapy and 13 were evaluable for response. Tumor regression was observed in 76.9% (10/13) of evaluable patients, regardless of prior anti-PD-1 exposure. The study reported tumor regression in 80% (4/5) of anti-PD-1 naïve patients and 60% (3/5) had investigator-assessed objective response, including one (1) complete response according to response evaluation criteria outlined in RECIST 1.1. In patients with prior primary or secondary resistance to anti-PD-1, 75% (6/8) had tumor regression and 50% (4/8) had investigator-assessed objective response. These included one (1) complete response and two (2) partial responses by RECIST 1.1, along with one (1) additional investigator-assessed pathological complete response. Some patients in the study showed delayed tumor response and/or abscopal effect, suggesting NBTXR3 may potentially prime an immune response.

Spider Plot – anti-PD-1 Naïve Patients



- In patients who were naïve to anti-PD-1, tumor regression was observed in 4 of 5 patients evaluable for tumor response.
- 60% (3/5) of patients had investigator-assessed objective response, including 1 CR by RECIST 1.1.

Spider Plot – anti-PD-1 Refractory Patients

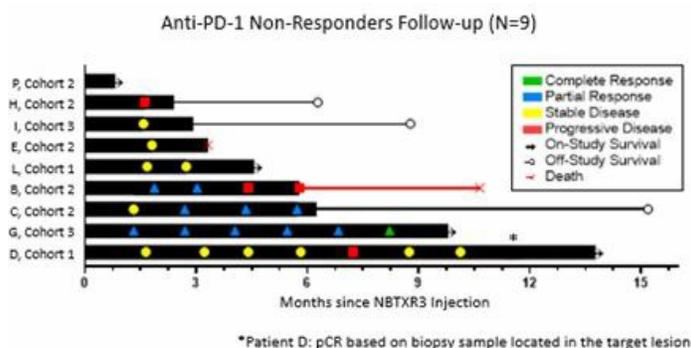


In patients who had primary or secondary resistance to prior anti-PD-1, tumor regression was observed in 6 of 8 patients evaluable for tumor response. 50% (4/8) had investigator-assessed objective response (1 CR and 2 PR by RECIST 1.1, and 1 pCR).

* Patient D: pCR based on biopsy sample located in the target lesion

“These updated data support the potential for NBTXR3 plus radiotherapy in combination with anti-PD-1 to yield a sustained immune response in both anti-PD-1 naïve patients and patients that have progressed on prior anti-PD-1 therapy,” concluded Colette Shen, MD, PhD, an assistant professor of radiation oncology at the University of North Carolina Lineberger Comprehensive Cancer Center and Study 1100 presenting investigator at ASCO. “NBTXR3 plus radiotherapy could stimulate immune response, convert anti-PD-1 non-responders into responders, and could be a promising next step for patients who develop immune checkpoint inhibitor resistance.”

Swimmer Plot – anti-PD-1 Refractory Patients Follow-up



Nanobiotix Investor Event

Nanobiotix will host a virtual investor event featuring several key opinion leaders, including study investigators, after the ASCO Annual Meeting on Friday, June 11, 2021 at 8:00 am Eastern Time (14:00 Central European Time). The discussion will focus on the new immunotherapy data from Study 1100. Register [here](#).

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; and a phase III global registrational study is planned to launch 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 planned phase III 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 and 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 strategic collaboration strategy 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.

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 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, the development and commercialization of NBTXR3, and the execution of the Company's development and commercialization strategy. 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 preclinical or early clinical result 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 Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission 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) under number D.21-0272 on April 7, 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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