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6-K	nt10024835x1_6k.htm
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EX-99.1	nt10024835x1_ex99-1.htm
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GRAPHIC	nt10024835x1_ex99-1image01.jpg
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GRAPHIC	nt10024835x1_ex99-1image03.jpg
GRAPHIC	nt10024835x1_ex99-1image04.jpg

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**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: May 19, 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):

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**EXHIBIT INDEX**

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<b><u>Exhibit</u></b>	<b><u>Title</u></b>
<a href="#">99.1</a>	Press Release, dated May 19, 2021

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**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)

May 19, 2021

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

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**PRESS RELEASE**

**NANOBIOTIX ANNOUNCES UPDATED RESULTS FROM PRIORITY PATHWAYS IN HEAD AND NECK CANCER AND IMMUNOTHERAPY FOR POTENTIAL FIRST-IN-CLASS RADIOENHANCER NBTXR3 AT 2021 ANNUAL MEETING OF THE AMERICAN SOCIETY FOR CLINICAL ONCOLOGY**

- Updated results from phase I dose expansion in head and neck cancer showed durable signs of efficacy at a median follow up of 8.1 months, with an overall objective response rate of 82.5% and a complete response rate of 62.5%
- Data from the expansion part of the study continue to support NBTXR3 as feasible and well-tolerated in highly vulnerable patients with high unmet needs and significant burden of disease
- Updates to immunotherapy data that have supported NBTXR3 plus anti-PD-1 as a potential option to yield sustained immune response in patients with locally advanced or metastatic tumors, regardless of prior anti-PD-1 exposure, will be reported prior to the conference
- Following ASCO, Nanobiotix will host an investor event on Friday, June 11, 2021 at 8am ET, to provide an in-depth review of the immunotherapy results with several key opinion leaders including study investigators ([Register here](#))

**Paris, France; Cambridge, Massachusetts (USA); May 19, 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 results from the Company’s priority development pathways in head and neck cancer (head and neck squamous cell carcinoma; HNSCC) and in immunotherapy for advanced cancers at the 2021 Annual Meeting of the American Society for Clinical Oncology (ASCO). The Company will also present a poster with long-term safety analysis from its pivotal phase II/III study in soft tissue sarcoma.

“The data we will present at ASCO provide further support for the paradigm-shifting potential of NBTXR3 as a foundational solid tumor-agnostic and combination-agnostic cancer therapeutic,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. “We are excited to present both long-term safety data from our phase III soft tissue sarcoma study, along with updated safety and efficacy data from our second single-agent registration pathway in head and neck cancer. Moreover, we are particularly eager to present a growing body of data suggesting that after activation by radiotherapy, NBTXR3 may prime an immune response that could enhance the efficacy of immune checkpoint inhibitors as a first-line therapy, overcome resistance for refractory patients, and meaningfully expand the tumor types that respond to the class by transforming cold tumors into hot tumors.”

**Local Control as a Single-Agent for Patients with Head and Neck Cancer**

*Abstract #6051: Phase I Dose Expansion Study of Functionalized Hafnium Oxide Nanoparticles (NBTXR3) in Cisplatin-Ineligible Locally Advanced HNSCC Patients*

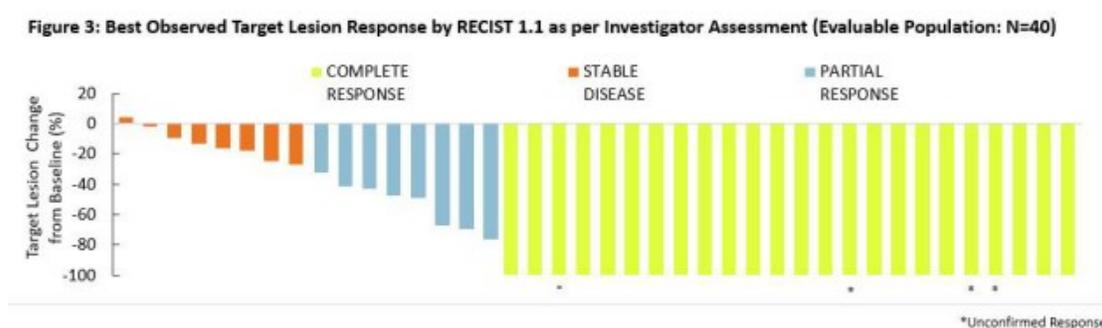
The number of elderly patients diagnosed with locally advanced HNSCC (LA-HNSCC) is increasing. While concurrent chemoradiation is the non-surgical standard of care, not all patients can tolerate platinum-based chemotherapy (e.g., cisplatin). The Nanobiotix phase I dose expansion study in patients with LA-HNSCC (Study 102) is evaluating a single dose of NBTXR3 at 22% of baseline tumor volume (the recommended phase II dose; RP2D). Primary endpoints of the study are objective response rate (ORR) and complete response rate (CRR) of the primary tumor. Study 102 is expected to recruit a total of 44 evaluable patients. To date, 52 total patients have been injected with NBTXR3 in the study overall, of which 40 have been evaluable.



Updated data presented at ASCO further support NBTXR3 administration, followed by activation with radiotherapy, as feasible and well-tolerated. Six (6) serious adverse events (SAEs) related to NBTXR3 were observed across five (5) patients. A total of ten (10) deaths related to adverse events were reported. Four (4) deaths related to radiotherapy were observed, along with one (1) death from sepsis that was investigator-assessed as possibly related to NBTXR3, radiotherapy, and cancer.

At a median follow up of 8.1 months, evaluable patients demonstrated a high primary tumor ORR of 82.5% and a 62.5% CRR. These results are consistent with those observed in the dose escalation part of the study and suggest durability of efficacy.

### Waterfall Plot – Best Observed Response in Study 102



Nanobiotix plans to launch a pivotal phase III global registration trial evaluating NBTXR3 as a single-agent activated by radiotherapy for patients with LA-HNSCC in 2021.

### Priming Immune Response and Immunotherapy Combination Across Oncology

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

*Abstract #2591: Overcoming Resistance to Anti-PD-1 with Tumor-Agnostic NBTXR3: From Bench to Bedside*

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 from anti-PD-1—or no benefit at all—as they either develop resistance to the therapy over time or are non-responsive to treatment altogether.

Previously reported data from the Company’s phase I immunotherapy study in advanced cancers (Study 1100) and its preclinical collaboration with The University of Texas MD Anderson Cancer Center support NBTXR3 activated by radiotherapy as a potential primer of immune response. These data suggest that when combined with anti-PD-1, NBTXR3 could contribute to tumor regression in patients with advanced and metastatic tumors regardless of the patient’s prior exposure to anti-PD-1.

Nanobiotix will provide an update on Study 1100 with additional patients and further follow up prior to the conference (abstract #2590). The Company will also present a compilation of preclinical and clinical data supporting NBTXR3 as a potentially tumor-agnostic, therapeutic combination-agnostic agent that could overcome resistance to immune checkpoint inhibitors and increase response rates across tumor indications (abstract #2591).



### **Local Control as a Single-Agent for Patients with Soft Tissue Sarcoma**

*Abstract #11544: Long-Term Evaluation of the Novel Radioenhancer NBTXR3 plus Radiotherapy in Patients with Locally Advanced Soft Tissue Sarcoma Treated in the Phase III Act.in.Sarc Trial*

A long-term safety analysis following the Nanobiotix phase II/III pivotal study evaluating NBTXR3 as a single-agent activated by radiotherapy in patients with locally advanced soft tissue sarcoma (STS) did not observe a negative impact on patient quality of life and long-term morbidity. The long-term safety profile of NBTXR3, together with its efficacy data, further supported a favorable benefit-risk ratio for patients with STS. The analysis highlighted potential for future indications, including non-resectable sarcoma, pediatric tumors, and re-irradiation.

### **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 am ET. The discussion will expand on the new immunotherapy results from Study 1100 that will be reported prior to ASCO, providing additional detail and clinical perspective, following the ASCO presentation. Register [here](#).

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### **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 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 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](http://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](http://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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