
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: July 1, 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 30, 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)

July 1, 2021

By: /s/ Bart Van Rhijn
Bart Van Rhijn
Chief Financial Officer



PRESS RELEASE

NANOBIOTIX ANNOUNCES INITIATION OF NEW CLINICAL STUDY EVALUATING NBTXR3 IN LUNG CANCER

- **First patient administered radiotherapy in phase I study evaluating NBTXR3 as a single-agent activated by radiotherapy in patients with non-small cell lung cancer amenable to re-irradiation**

Paris, France ; Cambridge, Massachusetts (USA) ; June 30, 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 initiation of a new phase I study evaluating NBTXR3 activated by radiation therapy (RT) for patients with non-small cell lung cancer (NSCLC) amenable to re-irradiation. The phase I is among five collaborator-led studies that are active and recruiting at The University of Texas MD Anderson Cancer Center (MD Anderson), and the third to enroll its first patient.

“Our ongoing collaboration with MD Anderson remains a critical component of our strategy as we seek to develop NBTXR3 as a solid tumor-agnostic, therapeutic combination-agnostic agent with the potential to change the practice of radiotherapy and immunotherapy,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. “These collaborator-led studies not only provide patients with significant unmet need the opportunity to benefit from MD Anderson’s physicians, but also provide additional capacity for Nanobiotix to expand development of NBTXR3 into indications where innovation is urgently needed while remaining focused internally on our priority pathways in head and neck cancer and immunotherapy.”

A Phase I Study of Reirradiation with NBTXR3 for Inoperable Locoregional Recurrent Non-Small Cell Lung Cancer

This phase I study, led by Saumil Gandhi, Assistant Professor, Department of Radiation Oncology, Division of Radiation Oncology, MD Anderson, investigates the safety and optimal dose of NBTXR3 when activated by radiation therapy for the treatment of non-small cell lung cancer that cannot be treated by surgery (inoperable) and has come back (recurrent). The study has a two-cohort, open label design consisting of two parts: (i) RT safety lead-in cohort recruiting up to 10 patients and NBTXR3 activated by RT dose-finding cohort recruiting up to 12 patients; and (ii) expansion at the recommended phase II dose (RP2D) with toxicity monitoring recruiting 12 patients. The dose levels explored to be explored are 22% and 33% of baseline gross tumor volume. The planned enrollment period is up to three years.

The patient population includes adults (age ≥ 18 years) with medically inoperable NSCLC with overlap between recurrent disease in need of treatment and prior RT. Given the design of the study, patients in the first cohort in part one will receive RT and be monitored for safety before the second cohort is opened where patients will receive injections of NBTXR3.

Five Studies Now Active and Recruiting in Clinical Collaboration

In addition to the lung cancer study described above, two phase II studies, each evaluating NBTXR3 in combination with anti-PD-1 for patients with head and neck cancer (inoperable locoregional recurrent amenable to reirradiation and recurrent metastatic with limited PD-L1 expression or refractory); one phase I study evaluating NBTXR3 in combination with chemotherapy for patients with esophageal cancer; and one phase I study evaluating NBTXR3 as a single-agent activated by RT for patients with pancreatic cancer are active and enrolling. As previously announced, the first patient has been injected with NBTXR3 in each of the esophageal cancer and pancreatic cancer studies. The first NBTXR3 injections in the phase II head and neck cancer studies are expected in the second half of 2021. All studies in the collaboration are led by MD Anderson and milestones will be reported as they are made available by the institution.

Next Steps for Collaborator-led Expansion of NBTXR3 Development as a Potentially Solid Tumor-Agnostic and Therapeutic Combination-Agnostic Agent

The clinical collaboration between Nanobiotix and MD Anderson is a collaborator-led expansion of the NBTXR3 development pipeline across indications and therapeutic combinations. One additional study evaluating NBTXR3 in combination with anti-CTLA-4 and anti-PD-1/L1 plus RadScopal™ in advanced solid tumors with lung or liver metastasis is planned to launch in the second half of 2021. Further studies evaluating the potential of NBTXR3 to address unmet needs throughout the oncology landscape are in discussion as part of the collaboration agreement and updates will be provided as the planning process evolves.

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 the second half of 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 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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