
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: January 8, 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
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99.1	Press Release, dated January 8, 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)

January 8, 2021

By: /s/ Philippe Mauberna

Philippe Mauberna

Chief Financial Officer



PRESS RELEASE

NANOBIOTIX ANNOUNCES KEY DEVELOPMENT MILESTONES FOR 2021 AFTER SUCCESSFUL NASDAQ INITIAL PUBLIC OFFERING

- Nanobiotix will use a portion of the proceeds from the its IPO to launch its global phase III registration study in head and neck cancer in the United States in 2021
- Following previously reported preliminary data regarding the ability of NBTXR3 to help transform anti-PD-1 non-responders into responders, the Company will provide the next update on its immuno-oncology phase I basket study evaluating NBTXR3 in combination with anti-PD-1 checkpoint inhibitors in the second quarter of 2021
- The Company’s expansive global development plan for NBTXR3, both as a single agent activated by radiotherapy and in combination with other anti-cancer therapies, will continue as planned

“Following the successful closing of our initial public offering on Nasdaq in December 2020, Nanobiotix is well positioned to continue global development of NBTXR3 as planned. Despite the challenges presented in 2020, our team achieved significant milestones to advance development of our tumor-agnostic lead product candidate across several indications—both as a single agent activated by radiotherapy and in combination with other anti-cancer therapies. In 2021, we intend to continue advancing our priority head and neck cancer pathway, and to generate further evidence that NBTXR3 could improve immunotherapy patient outcomes by increasing the proportion of patients that respond to immune checkpoint inhibitors. We will also continue to lay the foundation, to expand our development plan and achieve our mission of offering the potential benefits of NBTXR3 to millions of patients around the world.” – Laurent Levy, CEO of Nanobiotix

Paris, France; Cambridge, Massachusetts (USA); January 8, 2021 – NANOBIOTIX (Euronext: NANO – NASDAQ: NBTX – the “**Company**”), a clinical-stage biotechnology company focused on developing first-in-class product candidates that use proprietary nanotechnology to transform cancer treatment by increasing the efficacy of radiotherapy and increasing the proportion of patients that respond to immune checkpoint inhibitors, today announced its global development plan for 2021 and beyond.

Radiotherapy, also called radiation therapy, involves the use of X-rays or other high-energy particles or rays to kill cancer cells in tumors. It is among the most common cancer treatments, both as a standalone therapy and in combination with surgery, chemotherapy or biological therapies. In developed countries with access to radiotherapy, approximately 60% of all cancer patients will receive radiotherapy at least once, either alone or as a part of a more complex treatment protocol. Nevertheless, many of these patients still die from the progression of their cancer because, among other reasons, they are not able to receive a high enough radiation dose to completely destroy their tumor without resulting in an unacceptable level of damage to surrounding healthy tissues.

The pioneering approach from Nanobiotix uses nanophysics to bring a physical mode of action to destroy cancer cells. Unlike traditional chemotherapies or biologics, NBTXR3 has a broadly applicable mechanism of action that has the potential to be used in the treatment of all solid tumor types in conjunction with radiotherapy and other anti-cancer products.

The Company believes that NBTXR3’s mode of action could improve outcomes for patient populations across all solid tumors that may be treated with radiotherapy. These patient populations represent a significant market opportunity for NBTXR3. Moreover, the Company believes that NBTXR3 could bring new opportunities to patients with cancers that cannot currently be treated with radiotherapy because of the radiosensitivity, or other characteristics, of the tissues near the tumor.

Following the successful closing of an initial public offering (IPO) on the Nasdaq stock exchange in the fourth quarter of 2020, the Company’s strategic long-term goals aim to: (i) complete the development of, and satisfy applicable European Union (EU) and United States (US) regulatory requirements for, NBTXR3 for the treatment of locally advanced head and neck cancers; (ii) establish NBTXR3 as a complementary product to immune checkpoint inhibitors; (iii) complete the post-approval study for NBTXR3 for the treatment of locally advanced soft tissue sarcoma (STS) in the EU; (iv) expand the opportunity for NBTXR3 as a treatment for solid tumor indications; and (v) build an effective clinical development program and establish a global commercial infrastructure for NBTXR3.

Development of NBTXR3 as a tumor-agnostic product, both as a single agent activated by radiotherapy and in combination with other anti-cancer therapies, is expected to proceed as follows:

STUDY	STATUS	ANTICIPATED NEXT STEPS
NBTXR3 Activated by Radiotherapy Alone		
Phase III Registration Study of NBTXR3 in Head and Neck Cancer	Fast Track designation received for patient population from US Food and Drug Administration (FDA)	2021 – Expect first patients injected (FPI) Futility analysis expected 18 months after FPI; interim analysis expected 24-30 months after FPI
Nanobiotix Study NANORAY-312	Funding for initiation secured through IPO	
Phase I Expansion Study of NBTXR3 in Head and Neck Cancer	Dose Expansion – 51 patients injected as of December 31, 2020	2Q 2021 – Expect next results with new evaluable patients and additional follow up on patients treated
Nanobiotix Study 102 Expansion	35 of 44 patients deemed evaluable to date	Follow up and evaluation ongoing
Phase I Study of NBTXR3 in Liver Cancer	Complete	1Q 2021 – Final presentation of phase I results
Nanobiotix Study 103	Recommended phase II dose (RP2D) established at 42% of tumor volume	Next steps to be defined post Study 312 launch
Post-Registration Study of NBTXR3 in Soft Tissue Sarcoma	In preparation	2H 2021 – Expected study launch in EU
Nanobiotix Study 401		
Phase I Study of NBTXR3 in Pancreatic Cancer	Active	2021 – Recruitment ongoing
The University of Texas MD Anderson Cancer Center (MD Anderson) Study 2019-1001	First patient injected	Updates to be provided as they are made available by MD Anderson
Phase I Study of NBTXR3 in Lung Cancer Amenable to Re-irradiation	Received FDA ‘Safe to Proceed’	1H 2021 – Expected study launch
MD Anderson Study 2020-0123	Pending activation	Updates to be provided as they are made available by MD Anderson
NBTXR3 Activated by Radiotherapy in Combination with Immune Checkpoint Inhibitors		
Phase I Basket Study of NBTXR3 in Combination with Anti-PD-1 for Patients with Head and Neck Cancer, Lung Metastasis and/or Liver Metastasis	Positive first results presented at SITC 2020	2Q 2021 – Updated results with new patients and additional follow up expected
Nanobiotix Study 1100	Recruitment ongoing	
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	Received FDA ‘Safe to Proceed’	1H 2021 – Expected launch and first patient injected
MD Anderson Study 2020-0541	Pending activation	Updates to be provided as they are made available by MD Anderson
Phase II Study of NBTXR3 in Combination with Anti-PD-1/L1 for Patients with Inoperable Head and Neck Cancer Amenable to Re-irradiation	Received FDA ‘Safe to Proceed’	1H 2021 – Expected launch and first patients injected
MD Anderson Study 2020-0354	Pending activation	Updates to be provided as they are made available by MD Anderson
Phase I Study of NBTXR3 in combination with Anti-CTLA-4 and Anti-PD-1/L1 plus RadScopal™ in Advanced Solid Tumors with Lung or Liver Metastasis	In preparation	2021 – Expected launch and first patient injected
MD Anderson Study (2020-0618)		Updates to be provided as they are made available by MD Anderson
NBTXR3 Activated by Radiotherapy in Combination with Concurrent Chemotherapy		
Phase I Study of NBTXR3 in Esophageal Cancer	Active	1H 2021 – Expect first patient injected
MD Anderson Study 2020-0122	Not yet recruiting	Updates to be provided as they are made available by MD Anderson

Below is an overview of the Company's most advanced clinical studies.

Development of NBTXR3 as a Single Agent Activated by Radiotherapy Alone

Locally Advanced Head and Neck Cancers

Background and Opportunity:

Head and neck cancers include cancers of the oral cavity, tongue and oropharynx, a part of the throat. These structures play a critical role in a human's ability to swallow, breathe and speak. The American Cancer Society estimates that in 2020 in the United States, approximately 53,260 patients will be diagnosed with oral or oropharyngeal cancer and approximately 10,750 patients will die from the cancer. According to 2018 estimates by the Global Cancer Observatory, part of the World Health Organization's International Agency for Research on Cancer, around 890,000 patients are diagnosed globally each year with head and neck cancer. The five-year survival rate for patients with oral and oropharyngeal cancer is approximately 65%. These cancers represent a major public health concern.

Chemotherapy in combination with concomitant radiation is the standard treatment for locally advanced head and neck cancers in both the United States and the EU. However, it is often not an option for elderly patients who are unable to endure the physical strain inherent in chemotherapy treatment. The alternative treatment to chemoradiation is cetuximab in combination with radiotherapy, but it has a limited efficacy in elderly patients. These patients are estimated to account for approximately 25% of patients with head and neck cancers. In data presented at the Multidisciplinary Head and Neck Cancers Symposium 2020, elderly patients treated with radiotherapy alone or radiotherapy in combination with cetuximab had a median PFS of 7.3 months. Elderly patients with locally advanced tumors who receive radiation also generally have short OS rates (median of 12 months following diagnosis, based on our review and sub-group analysis of scientific literature relating to head and neck cancers) and typically experience poor quality of life, as they have limited therapeutic options and a high unmet medical need.

Phase III Registration Study in Head and Neck Cancer (Nanobiotix Study NANORAY-312)

In February 2020, Nanobiotix submitted the NANORAY-312 protocol to the FDA for review, a global Phase III clinical study for elderly patients with locally-advanced head and neck cancer who are ineligible for platinum-based (cisplatin) chemotherapy. The Company is in the process of making final protocol refinements in response to FDA feedback and intend to initiate Study NANORAY-312 with a portion of the proceeds from the Company's Nasdaq IPO. Nanobiotix expects the study to launch in the United States in 2021.

Also in February 2020, the Company received Fast Track designation from the FDA for NBTXR3 in this patient population. Fast Track designation is a process designed to facilitate the development and accelerate the review of treatments for serious conditions and that have the potential to address unmet medical needs. We may also potentially pursue Breakthrough Therapy designation.

Phase I Dose Expansion Study in Head and Neck Cancer (Nanobiotix Study 102 Expansion)

The Company is in the process of conducting the dose expansion part of a phase I clinical trial of NBTXR3 activated by intensity-modulated radiation therapy (IMRT) in patients with locally advanced squamous cell carcinoma of the oral cavity or oropharynx who are ineligible for cisplatin or intolerant to cetuximab. The expansion cohort utilizes the highest dose level (22%) from the dose escalation portion of Study 102 in order to potentially strengthen preliminary efficacy data from that initial phase. As of December 2020, 51 have been injected in Study 102 Expansion. To date, 35 of the necessary 44 patients have been deemed evaluable. Follow up and evaluation remain ongoing. Nanobiotix presented preliminary efficacy and safety results from Study 102 Expansion in October 2020 at the annual meeting of the American Society for Radiation Oncology (ASTRO).

Next results will be presented during the International Organization for Medical Physics (IOMP) week in the second quarter of 2021.

Hepatocellular Carcinoma and Liver Metastasis

Background and Opportunity:

According to the World Health Organization, liver cancer is currently the fourth most common cause of cancer death in the world and is estimated to have caused over 781,000 deaths in 2018. The American Cancer Society estimated that in 2020 in the United States, 42,810 people would be diagnosed with liver cancer and 30,160 patients would die of the disease. In Europe, an estimated 47,000 patients die of liver cancer each year. The five-year survival rate for patients with localized liver cancer is approximately 31%; once the cancer has spread to other organs or tissues, this survival rate drops to approximately 3%.

Two types of liver cancer are hepatocellular carcinoma (HCC), the most common type of liver cancer, and secondary liver cancer, or liver metastasis, which occurs when cancer from another part of the body spreads to the liver. Surgical resection is often not an option for patients with either HCC or liver metastasis. Moreover, because patients suffering from HCC or liver metastases typically have underlying liver dysfunction and concomitant malignancies, local and systemic treatment options are few in number, with significant limitations. Stereotactic body radiation therapy (SBRT)—a high-precision radiation therapy, delivered as high-energy dose fractions—is a prevalent alternative therapy that has been shown to improve outcomes for these patients, as third-party clinical studies have observed a direct correlation between higher doses of radiation and increased survival rates. However, SBRT dosage is limited due to potential toxicity to surrounding tissues and the need to preserve liver function. The Company's ongoing phase I/II clinical study described below evaluated NBTXR3 in patients with liver cancers in need of an alternative treatment, when standard care protocols either cannot be used or do not exist. By increasing the absorption of the administered SBRT dose within the tumor itself, without causing additional damage to surrounding healthy tissues, and causing more effective tumor destruction, Nanobiotix believes NBTXR3 can improve prognoses for this patient population.

Phase I Study of NBTXR3 for Patients with HCC and Liver Metastasis (Nanobiotix Study 103)

Nanobiotix has completed its phase I study evaluating the use of NBTXR3 activated by SBRT in liver cancers. The study was conducted at six sites in the EU. The Company recruited 23 patients, divided in two subgroups: patients with primary liver cancer (HCC) and patients with secondary liver cancer (liver metastases).

The endpoint of the study was determination of the RP2D of NBTXR3 and to assess early signs of anti-tumor activity. Patients received a single intra-lesional injection of NBTXR3, at increasing dose levels, in each case activated by SBRT.

The final presentation of results from Study 103 will be delivered at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI) in the first quarter of 2021.

Locally Advanced Soft Tissue Sarcoma

Background and Opportunity:

Soft tissue sarcomas (STSs) are rare cancers that develop in different types of soft tissues, including muscles, joint structures, fat, nerves and blood vessels. Although STS can develop at any anatomic site, it occurs in the extremities (arms and legs) in approximately 60% of cases. The American Cancer Society estimates that in 2020 in the United States, approximately 13,130 patients will be diagnosed with STS, and approximately 5,350 STS patients will die from this cancer. In the EU, over 23,000 patients are diagnosed with STS each year. The National Cancer Institute estimates that the five-year survival rate for STS patients is approximately 65%. Median overall survival for patients with advanced, metastatic STS is estimated to be 18-19 months. Radiotherapy followed by surgery is part of the typical treatment regimen for STS patients in Europe.

Achieving local control of the tumor is critical to improving survival rates and reducing the need for limb amputations. Patients with locally advanced STS are high-risk patients and have few therapeutic options capable of achieving local control. Consequently, innovative treatments to improve cancer cell destruction and the feasibility of surgical resection are needed. NBTXR3, when activated by radiotherapy, is designed to enhance the efficacy of radiation both by destroying more tumor cells and rendering the tumor more susceptible to surgical resection, thereby improving patient outcomes.

Post-Registrational Study of NBTXR3 in Soft Tissue Sarcoma of the Extremities and Trunk Wall (Nanobiotix Study 401)

In April 2019, Nanobiotix completed the regulatory process for the CE mark of NBTXR3 based on positive results from the Company's phase II/III study evaluating the product candidate for patients with advanced STS of the extremities and trunk, thereby allowing the product to be commercialized in the 27 EU countries under the brand name Hensify®. Nanobiotix is currently preparing a post-registrational study (Study 401) that will continue evaluating the safety and efficacy of Hensify while providing patients with access to the product. We expect approximately 100 patients to be recruited as part of Study 401, which is expected to launch in Europe in the second half of 2021. Following evaluation of the results from Studies 102 and 312, we intend to continue our strategic review and to consider the optimal approach to the commercialization of Hensify.

Pancreatic Cancer

Background and Opportunity:

Pancreatic cancer is a rare, deadly disease. Worldwide, there were approximately 460,000 new cases in 2018. Given that surgery with R0 resection (i.e., macroscopically complete tumor removal with negative microscopic surgical margins) remains the only hope for long-term survival, clinical studies have investigated various neoadjuvant strategies—wherein patients receive anti-cancer drugs or radiation prior to surgery—to increase the surgery-eligible population while also increasing the R0 resection rate. According to the American Cancer Society, for all stages of pancreatic cancer combined, the one-year relative survival rate is 20%, and the five-year rate is 7%.

In support of the rationale for neoadjuvant therapy, a retrospective analysis demonstrated a near doubling in OS in pancreatic ductal adenocarcinoma (“PDAC”) patients who underwent surgery, which was attributed, at least in part, to the increased proportion of borderline resectable pancreatic cancer (“BRPC”) patients who became eligible for surgery as a result of neoadjuvant intervention. Importantly, there are also select cases of locally advanced pancreatic cancer (“LAPC”) patients being considered for surgical resection based on their response to therapy. Given the poor prognosis of PDAC, therapeutic regimens able to increase the proportion of BRPC and LAPC patients eligible for surgery could improve survival outcomes in this population with unmet need.

Phase I Study of NBTXR3 for Patients with Pancreatic Cancer (MD Anderson Study 2019-1001)

This MD Anderson study is an open-label, single-arm, prospective phase I study consisting of two parts: (i) dose-escalation to determine the RP2D; and (ii) expansion at RP2D.

In May 2020, we announced that the FDA allowed the clinical study protocol to proceed, and we dosed the first patient in this study during September 2020. Recruitment is expected to remain ongoing throughout 2021 and additional updates will be provided as they are made available by MD Anderson.

Lung Cancer

Background and Opportunity:

According to the World Health Organization, lung cancer is currently the most common cause of cancer death in the world and is estimated to have caused over 1,761,000 deaths in 2018. According to the American Cancer Society, in 2020 it is estimated that there will be approximately 228,000 new cases of lung cancer diagnosed in the United States. It is estimated that in the United States there will be approximately 135,720 deaths from lung cancer in 2020. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses. The five-year relative survival rate for NSCLC at all stages was 24%.

Phase I Study of NBTXR3 for patients with Lung Cancer Amenable to Re-irradiation (MD Anderson Study 2020-0123)

This MD Anderson study is an open-label, two-cohort, prospective phase I study consisting of two parts: (i) a radiation therapy safety lead-in, and NBTXR3 activated by radiation therapy dose-finding to determine the RP2D, and (ii) expansion at RP2D with toxicity monitoring.

The patient population will include adults (age ≥ 18) with inoperable, locoregional recurrent (“LRR”) non-small cell lung cancer (NSCLC) stage IA to IIIC that are radiographically non-metastatic at screening and have previously received definitive radiation therapy. The number of participants enrolled will be determined based on the maximum number required to establish the RP2D. Cohort 1 will evaluate the safety of intensity-modulated radiation therapy (“IMRT”) monotherapy in 10 patients using an approach similar to a 3+3 design. If 45 Gy in 15 fractions is deemed safe, cohort 2 will test that regimen with NBTXR3 activated by IMRT. Alternatively, if 45 Gy in 15 fractions is deemed to have excessive toxicity, a 30 Gy in 10 fractions regimen will be used in combination with NBTXR3 in cohort 2. Up to 24 subjects will be enrolled in cohort 2, including a maximum of 12 subjects for the dose-finding part. Twelve additional subjects will be enrolled for the NBTXR3 RP2D expansion. Study initiation is expected in the first half of 2021, and the planned enrollment period is 36 months.

The launch of this study has been delayed by logistical constraints associated with the COVID-19 pandemic. Updates will be provided as they are made available by MD Anderson.

Development NBTXR3 Activated by Radiotherapy in Combination with Immune Checkpoint Inhibitors (Immuno-Oncology Program)

Background and Opportunity:

In recent years, significant attention has been focused on the potential of immuno-oncology (I-O) treatments, and in particular, checkpoint inhibitors. Checkpoint inhibitors are a type of immunotherapy that function to block proteins that stop the immune system from attacking cancer cells. In doing so, they enable the T cells to recognize cancer cells that would otherwise be invisible to immune attack. However, many tumors, which are referred to as “cold” tumors, exhibit little or no response to checkpoint inhibition.

Cancer immunotherapy is becoming a major treatment paradigm for a variety of cancers. Although immunotherapy, especially the use of immune checkpoint inhibitors, has achieved clinical success, most cancer patients present resistance to I-O treatments. In fact, published scientific data shows that only 15%-20% of non-small cell lung cancer patients and 13%-22% of head and neck squamous cell carcinoma patients respond to immune checkpoint inhibitors. We believe that NBTXR3 activated by radiotherapy in combination with immune checkpoint inhibitors has the potential to unlock the potential of I-O treatments by converting checkpoint inhibitor non-responders into responders.

Our preclinical and early clinical study results suggest that NBTXR3-enhanced radiotherapy may prime the immune response, thereby rendering otherwise cold tumors more prone to recognition by the patient’s immune system and therefore more responsive to I-O treatments such as checkpoint inhibitors. This effect is also referred to as causing a “cold” tumor to become “hot.”

Phase I Basket Study of NBTXR3 in Combination with Anti-PD-1 for Patients with Head and Neck Cancer, Lung Metastasis and/or Liver Metastasis (Nanobiotix Study 1100)

Nanobiotix presented positive first clinical results from Study 1100 at the SITC 35th Annual Meeting in November 2020. Recruitment in the study remains ongoing, and the Company expects updated results with new patients and additional follow-up at the Annual Meeting of the American Society for Clinical Oncology in the second quarter of 2021.

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 (MD Anderson Study Number 2020-0541)

This MD Anderson study is an open label, two cohort, non-randomized phase II study. The primary objective of the study is to evaluate tumor response of NBTXR3 activated by radiation therapy in combination with pembrolizumab in patients with recurrent or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) with limited PD-L1 expression.

Nanobiotix expects this study to launch and inject the first patient in 2021. Updates will be provided as they are made available by MD Anderson.

Phase II Study of NBTXR3 in Combination with Anti-PD-1 for Patients with Head and Neck Cancer Amenable to Re-Irradiation (MD Anderson Study Number 2020-0354)

This MD Anderson study is an open label, two cohort, non-randomized phase II study. The primary objectives of the study are: (i) to estimate progression-free survival (PFS) and the early clinical benefit in patients treated with NBTXR3 activated by SBRT re-irradiation, with concurrent pembrolizumab; (ii) to assess the safety profile and estimate the early clinical benefit of NBTXR3 activated by a reduced dose of IMRT or IMPT re-irradiation with concurrent pembrolizumab.

Nanobiotix expects this study to launch and inject the first patient in 2021. Updates will be provided as they are made available by MD Anderson.

Phase I Study of NBTXR3 in Combination with Anti-PD-1 and Anti-CTLA-4 plus RadScopal for Patients with Advanced Solid Tumors and Lung or Liver Metastasis (MD Anderson Study Number 2020-0618)

This MD Anderson study is currently in the early stages of the regulatory review process. Nanobiotix expects this study to launch and inject the first patient in 2021. Updates will be provided as they are made available by MD Anderson.

Development of NBTXR3 Activated by Radiotherapy in Combination with Concurrent Chemotherapy

Esophageal Cancer

Background and Opportunity:

According to the World Health Organization, esophageal cancer is currently the sixth most common cause of cancer death in the world and is estimated to have caused over 508,585 deaths in 2018. The American Cancer Society estimates that in 2020 in the United States, there will be approximately 18,440 new esophageal cancer cases diagnosed, and approximately 16,170 deaths due to esophageal cancer. Approximately 20% of patients survive esophageal cancer at least five years after diagnoses.

Phase I Study of NBTXR3 for Patients with Esophageal Cancer (MD Anderson Study 2020-0122)

The FDA has indicated that our Phase I clinical study of NBTXR3 with MD Anderson for patients with esophageal cancer may proceed.

This study is an open-label, single-arm, prospective phase I study consisting of two parts: (i) dose-escalation to determine the RP2D of NBTXR3 activated by radiotherapy with concurrent chemotherapy, and (ii) expansion at RP2D with toxicity monitoring.

The patient population will include adults (age ≥ 18 years) with stage II-III adenocarcinoma of the esophagus that are treatment naïve and radiographically non-metastatic at screening. The number of participants enrolled will be determined based on the maximum number required to establish the RP2D of NBTXR3 activated by radiation therapy. Up to 24 subjects will be enrolled, including a maximum of 12 subjects for the dose-finding part. Twelve additional subjects will be enrolled for the RP2D expansion. Recruitment and first injections are expected to begin in the first half of 2021 and the planned enrollment period is 24 months.

The launch of this study has been delayed by logistical constraints associated with the COVID-19 pandemic. Updates will be provided as they are made available by MD Anderson.

PharmaEngine Trials

Pursuant to a License and Collaboration Agreement with PharmaEngine, Inc., three NBTXR3 clinical trials are currently being run in Asia by PharmaEngine. These trials include a phase III study of NBTXR3 activated by radiotherapy for patients with soft tissue sarcoma, a phase I/II study of NBTXR3 activated by radiotherapy with concurrent chemotherapy for patients with rectal cancer, and a phase I/II study of NBTXR3 activated by radiotherapy with concurrent chemotherapy for patients with head and neck cancer.

Results from the rectal cancer study will be presented at the 2021 American Society of Clinical Oncology Gastrointestinal Symposium. Further updates will be provided as they are made available by PharmaEngine.

About NBTXR3

NBTXR3 is a novel, potentially first-in-class product candidate designed to destroy tumors through physical cell death when activated by radiotherapy. NBTXR3 has a high degree of biocompatibility, requires one single administration before the first radiotherapy treatment session, and has the ability to fit into current worldwide standards of radiation care. The physical mode of action of NBTXR3 makes it applicable across solid tumors such as lung, prostate, liver, glioblastoma, and breast cancers.

About NANOBIOTIX: www.nanobiotix.com

Incorporated in 2003, Nanobiotix is a leading, clinical-stage nanomedicine company pioneering new approaches to significantly change patient outcomes by bringing nanophysics to the heart of the cell.

The Nanobiotix philosophy is rooted in designing pioneering, physical-based approaches to bring highly effective and generalized solutions to address unmet medical needs and challenges.

Nanobiotix's novel, potentially first-in-class, proprietary lead technology, NBTXR3, aims to expand radiotherapy benefits for millions of cancer patients. Nanobiotix's Immuno-Oncology program has the potential to bring a new dimension to cancer immunotherapies.

Nanobiotix is listed on the regulated market of Euronext in Paris (Euronext: NANO / ISIN: FR0011341205; Bloomberg: NANO:FP) and on the Nasdaq Global Select Market (Nasdaq: NBTX). The Company's headquarters are in Paris, France, with a U.S. affiliate in Cambridge, MA, and European affiliates in France, Spain and Germany

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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 (including with respect to patient enrollment and follow-up), the timing of our presentation of data, our relationship with, and the performance of, our collaboration partners, and the sufficiency of cash to fund operations. 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 duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation. Furthermore, many other important factors, including those described in our prospectus filed with the U.S. Securities and Exchange Commission on December 11, 2020 under the caption “Risk Factors” and those set forth in the universal registration document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.20-010 on May 12, 2020 (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.
