*PRESS RELEASE*

# NANOBIOTIX RECEIVES FEEDBACK FROM US FDA TO ADVANCE PHASE III HEAD AND NECK CANCER STUDY DESIGN AND CMC DEVELOPMENT PLAN FOR NDA

- **The US Food and Drug Administration (FDA) provided feedback necessary to proceed with the design of NANORAY-312, a pivotal phase III trial investigating NBTXR3 for elderly head and neck cancer patients ineligible for platinum-based chemotherapy.**
- **The FDA also agreed to the NBTXR3 chemistry, manufacturing and controls (CMC) development plan to support the future New Drug Application (NDA) for the product and its use in the NANORAY-312 phase III clinical trial.**

*"With our recent Fast Track designation for NBTXR3 in this patient population, acceptance of the design of our pivotal phase III trial and agreement on our CMC plan, Nanobiotix is well positioned to deliver on our promise of serving the unmet needs of head and neck cancer patients. Our head and neck cancer pathway is our top priority and these developments represent critical milestones that will allow us to administer and supply our trial. We look forward to taking the necessary steps to initiate NANORAY-312 and evaluate the potential of NBTXR3 to improve treatment outcomes for patients around the world."* – Laurent Levy, CEO of Nanobiotix.

**Paris, France; Cambridge, Massachusetts (USA); June 17, 2020 –** NANOBIOTIX (Euronext : NANO – ISIN : FR0011341205 – the ''**Company**''), a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced that the FDA has provided necessary feedback regarding the design of NANORAY-312, the Company's pivotal phase III global registration trial in head and neck cancer. The FDA also agreed to the NBTXR3 chemistry, manufacturing, and controls (CMC) Development Plan to support the phase III trial and a future New Drug Application (NDA) for the product.

**NANORAY-312: A Phase III Study of NBTXR3 Activated by Investigator's Choice of Radiotherapy Alone or Radiotherapy in Combination with Cetuximab for Platinum-based Chemotherapy-ineligible Elderly Patients with Locally Advanced Head and Neck Squamous Cell Carcinoma.**

NANORAY-312 will be a phase III investigator's choice, dual-arm, randomized (1:1) global registration trial including elderly head and neck cancer patients who are ineligible for platinum-based chemotherapy.

Patients in the control arm will receive radiation therapy with or without cetuximab (investigator's choice), and patients in the treatment arm will receive NBTXR3 activated by radiation therapy with or without cetuximab (investigator's choice).

The trial is expected to recruit approximately 500 patients. A futility analysis is expected 18 months after the first patient in the trial is randomized, and the interim analysis for progression-free survival (PFS) superiority is expected at 24-30 months. The final analysis will report on PFS and overall survival. Quality of Life will also be measured as a key secondary outcome. In the event of favorable data from the interim analysis, the FDA has advised that NBTXR3 could potentially qualify for accelerated approval.

In support of the phase III trial and a future NBTXR3 New Drug Application (NDA), Nanobiotix met with the FDA in a Type B end-of-phase I meeting on October 16, 2019. Following additional correspondence with the FDA, including written responses to the FDA's recommendations, the Company received written FDA guidance on April 3, 2020. The Company expects to commence NANORAY-312 after making protocol refinements and securing the requisite financing to fund the trial.

**Agreement to CMC Development Plan**

The FDA's written response regarding the CMC Development Plan does not raise any safety concerns for continued clinical development of NBTXR3, and the FDA agreed to the updated CMC Plan for NBTXR3 during an ongoing phase III clinical trial.

***

## About NBTXR3

NBTXR3 is a first-in-class product 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.

NBTXR3 is actively being evaluated in clinical trials worldwide as a potential treatment in various cancer indications. The Company is prioritizing the development of NBTXR3 in the United States and the EU for the treatment of patients with locally advanced head and neck cancers ineligible for chemotherapy.

Nanobiotix is also running an Immuno-Oncology development program, evaluating NBTXR3 activated by radiotherapy as a primer of immune response in combination with checkpoint inhibitors. The Company has launched a phase I clinical trial of NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors in patients with locoregional recurrent (LRR) or recurrent and metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) amenable to re-irradiation or with lung or liver metastasis (mets) from any primary cancer eligible for anti-PD-1 therapy.

Other ongoing NBTXR3 trials are treating patients with liver cancers (hepatocellular carcinoma and liver metastasis), locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and pancreatic cancer. The Company has a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (initially expected to support nine new clinical trials in the United States) to evaluate NBTXR3 across several cancer types.

## 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 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). The Company's headquarters are in Paris, France, with a US affiliate in Cambridge, MA, and European affiliates in France, Spain and Germany.

## Contacts


*Nanobiotix*

**Communications Department**
*Brandon Owens*
*VP, Communications*
+1 (617) 852-4835
contact@nanobiotix.com

**Investor Relations Department**
*Ricky Bhajun (EU)*
*Senior Manager, Investor Relations*
+33 (0)1 79 97 29 99
investors@nanobiotix.com

*Media Relations*

**France – TBWA Corporate**
**Pauline Richaud**
+ 33 (0) 437 47 36 42
Pauline.richaud@tbwa-corporate.com


NANO LISTED EURONEXT

**Disclaimer**

*This press release contains certain forward-looking statements concerning Nanobiotix and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks 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) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered*

*material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.*