

**PRESS RELEASE**

**NANOBIOTIX ANNOUNCES FAST TRACK DESIGNATION GRANTED BY U.S. FDA FOR INVESTIGATION OF FIRST-IN-CLASS NBTXR3 IN HEAD AND NECK CANCER**

- **The U.S. Food and Drug Administration reviewed the Company's request for Fast Track designation and concluded that investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced head and neck squamous cell cancer who are not eligible for platinum-based chemotherapy meets the criteria for a Fast Track development program**
- **Fast Track designation for NBTXR3 in head and neck cancer underscores the urgent need for potential new treatment options for patients in this population**

*"The FDA's decision to grant Fast Track designation is not only important for the development of NBTXR3 activated by radiation therapy, which is now eligible for accelerated approval and priority review, but even more critically it underscores the unmet needs and limited options of patients with locally advanced head and neck cancer. The available public data and our development plans moving forward give us confidence that NBTXR3 could significantly improve treatment outcomes for patients. Fast Track development in head and neck cancer is a major step forward." – Laurent Levy, CEO of Nanobiotix*

**Paris, France ; Cambridge, Massachusetts (USA) ; February 10, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced head and neck squamous cell cancer who are not eligible for platinum-based chemotherapy.

Fast Track is a process designed to facilitate the development and accelerate the review of drugs for serious conditions and that have the potential to address unmet medical needs. The purpose is to expedite the availability of new treatment options for patients.

A product that receives Fast Track designation is eligible for<sup>1</sup>:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from the FDA about such things as the design of proposed clinical trials and the use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of the New Drug Application (NDA) for review by the FDA, rather than waiting until the entire NDA is completed before the application can be reviewed

\*\*\*

**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 radiotherapy radiation therapy standards of care. The physical mode of action of NBTXR3 makes it applicable across solid tumors such as lung, prostate, liver, glioblastoma, and breast cancers.

NBTXR3 is actively being evaluated locally advanced head and neck squamous cell carcinoma (HNSCC) of the oral cavity or oropharynx in elderly and frail patients unable to receive chemotherapy or cetuximab with limited therapeutic options. Promising results have been observed in the phase I trial regarding local control. In the United States, the company has

---

<sup>1</sup> <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

started the regulatory process for the clinical authorization of a phase II/III trial in locally advanced head and neck cancers.

Nanobiotix is also running an Immuno-Oncology development program. The Company received FDA approval to launch a clinical trial of NBTXR3 activated by radiotherapy in combination with anti-PD-1 antibodies in locoregional recurrent (LRR) or recurrent and metastatic (R/M) HNSCC amenable to re-irradiation of the HN and lung or liver metastases (mets) from any primary cancer eligible for anti-PD-1.

The other ongoing NBTXR3 trials are treating patients with hepatocellular carcinoma (HCC) or liver metastases, locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma. Furthermore, the company has a large-scale, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center (9 new phase I/II clinical trials in the United States) to evaluate NBTXR3 across head and neck, pancreatic, thoracic, lung, gastrointestinal and genitourinary cancers.

### **About NANOBIOTIX:** [www.nanobiotix.com](http://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](mailto:contact@nanobiotix.com)

*Pascalynne Wilson*  
Senior Manager, Corporate  
Marketing  
+33 (0) 1 70 61 00 18  
[contact@nanobiotix.com](mailto:contact@nanobiotix.com)

#### **Investor Relations Department**

*Noel Kurdi (US)*  
Director, Investor Relations  
+1 (646) 241-4400  
[investors@nanobiotix.com](mailto:investors@nanobiotix.com)

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

---

### *Media Relations*

---

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

US – **RooneyPartners**  
**Marion Janic**  
+1 (212) 223-4017  
[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)



## **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 reference document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-018 on April 30, 2019 (a copy of which is available on [www.nanobiotix.com](http://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.*

