Nanobiotix announces its clinical registration plan in Head and Neck cancers for the United States following FDA feedback

- **Moving forward with Overall Survival (OS)-based, randomized, event-driven clinical trial for the United States**
- **Pre-IND feedback from US Food and Drug Administration (FDA) provides clarity to Nanobiotix on US regulatory pathway to approval**
- **Clinical trial authorization process to begin in 2H2019 with FDA filing**

''We are happy to announce our plan for the registration pathway in Head and Neck cancers in the US. This is a key milestone for the Company and our shareholders, and we look forward to critical next steps toward US development,'' commented Laurent Levy, Nanobiotix's CEO.

Paris, France; Cambridge, Massachusetts (USA); March 26, 2019 - NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205 – **the ''Company''),** a clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced that the Company has clarity on its regulatory pathway in the treatment of Head and Neck cancers for first-in-class radioenhancer NBTXR3. The announcement follows pre-IND feedback from the US FDA received on March 18, 2019.

Stage III and IV Head and Neck cancers include large primary tumors which may invade underlying structures and/or spread to regional nodes. Treatment of these locally advanced forms of the disease—which makes up more than 50% of all Head and Neck cancers—requires aggressive, concerted measures that often remain a clinical challenge with an estimated 5-year survival rate of 50% with the current standard of care.

Within the Stage III and IV Head and Neck cancers patient population, the Company targets a subpopulation of patients, who have a higher risk of recurrence, or a poorer prognosis as they have an inability to receive cisplatin, the frontline chemotherapy drug for advanced Head and Neck cancers. Additionally, the localization of the tumor focuses on oropharynx, hypopharynx, and oral cavity – representing the majority of Head and Neck cancers.

Based on US FDA feedback, the Company plans to design an Overall Survival (OS)-based, randomized, event-driven Phase II/III clinical trial. 50% of patients will receive standard of care radiotherapy combined with NBTXR3 while the other 50% will receive radiotherapy in combination with cetuximab. The expected total number of patients to participate in this global clinical trial is approximately 600, and an efficacy interim analysis is planned.

Notably, the US FDA has not objected to the use of the data from the dose-escalation phase of the Company's European Phase I clinical trial in elderly and frail patients with locally advanced Head and Neck cancers as well as the Company's current CMC (chemical, manufacturing and control) development plan.

The Company plans to initiate its global clinical trial authorization process with US FDA in 2H2019.

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About NBTXR3

NBTXR3 is a first-in-class product candidate designed to destroy tumors and metastasis when activated by radiotherapy.

NBTXR3 has a high degree of biocompatibility and requires one single administration before the whole radiotherapy treatment. Nanobiotix believes NBTXR3 has the ability to fit into current worldwide standards of radiation care.

Nanobiotix's broad clinical program includes 7 clinical trials. In June 2018, Nanobiotix established human proof of concept for this first-in-class product candidate in its Soft Tissue Sarcoma (STS) Phase III clinical trial.

NBTXR3 is actively being studied in head and neck cancer with locally advanced squamous cell carcinoma of the oral cavity or oropharynx in elderly and frail patients who are unable to receive chemotherapy or cetuximab and have very limited therapeutic options. Promising results from these clinical studies have been observed from the ongoing Phase I/II trial regarding the local control of tumors.

Nanobiotix is also running an Immuno-Oncology development program. In the United States, Nanobiotix has received approval from the US FDA to launch a clinical study of NBTXR3 activated by radiotherapy in combination with anti-PD1 antibodies in lung, and head and neck cancer patients (head and neck squamous cell carcinoma and non-small cell lung cancer).

The 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 prostate adenocarcinoma.

The first market authorization process (CE Marking) is ongoing in Europe in the STS indication.

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 U.S. affiliate in Cambridge, MA, and European affiliates in Spain and Germany.

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Disclaimer

This press release contains certain forward-looking statements concerning Nanobiotix and its business. 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 filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number D.17-0470 on April 28, 2017 as well as in its 2017 annual financial report filed with the French Financial Markets Authority on March 29, 2018 (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. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country. At the moment NBTXR3 does not bear a CE mark and is not permitted to be placed on the market or put into service until NBTXR3 has obtained a CE mark.