

**PRESS RELEASE**

**NANOBIOTIX ANNOUNCES POSITIVE FIRST RESULTS FOR NOVEL NBTXR3 IN RECTAL CANCER STUDY AT ASCO-GI 2021**

- **Positive first results from the complete dose-finding part of a phase Ib/II study of tumor-agnostic NBTXR3 (PEP503) activated by radiotherapy with concurrent chemotherapy for patients with rectal cancer show that intratumoral injection of the product candidate was feasible and it was well tolerated at all dose levels**
- **An injection procedure-related dose-limiting toxicity of urinary tract infection was observed in the study, however there were no observed adverse events or severe adverse events associated with NBTXR3**
- **More than 70% of patients showed objective tumor response after concurrent chemoradiation**
- **Approximately 90% of patients underwent total mesorectal excision (surgery), and 17.6% achieved pathological complete response**
- **50% of the patients receiving surgery had good tumor regression (tumor regression grade 0 or 1)**

**Paris, France; Cambridge, Massachusetts (USA); January 15, 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, today announced positive first results from the complete phase Ib part of a phase Ib/II study evaluating NBTXR3 (PEP503) activated by radiotherapy with concurrent chemotherapy. This study is sponsored and administered by PharmaEngine, Inc. in Taiwan pursuant to a License and Collaboration agreement with the Company. The data were presented at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI 2021).

**A NEW RADIOENHANCER, PEP503 (NBXTR3), IN COMBINATION WITH CONCURRENT CHEMORADIATION IN LOCALLY ADVANCED OR UNRESECTABLE RECTAL CANCER: THE DOSE-FINDING PART OF A PHASE IB/II TRIAL**

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**Background**

Radiotherapy, chemotherapy and surgery are elements of the standard of care for patients with rectal cancer. Concurrent chemoradiation (CCRT) followed by surgery, if possible, is the recommended option for patients with resectable (surgically removable) T3 to T4 tumors, or who have locally unresectable or inoperable disease. Better response to CCRT, prior to surgery, may be associated with better long-term treatment outcomes.

The potential efficacy of tumor-agnostic NBTXR3 in increasing tumor shrinkage—as observed in phase I head and neck cancer, and phase I liver cancer studies—may result in tumor downstaging and lead to an improvement in surgical outcomes.

**Study Design**

The complete dose-finding part of this phase Ib/II study evaluated the safety, feasibility and recommended phase II dose of NBTXR3 for patients with locally advanced (T3 to T4) or unresectable rectal cancer. The study enrolled 20 patients: with seven, four, three, and six patients at the 5%, 10%, 15%, and 22% dose levels, respectively.

**Topline Results**

Intratumoral injection of NBTXR3 with CCRT was feasible and the product candidate was well tolerated at all dose levels, and no adverse events (AEs) or serious adverse events (SAEs) associated with NBTXR3 were observed in the study. One dose-limiting toxicity associated with the injection procedure was observed (urinary tract infection). The most frequently reported AEs were diarrhea (approximately 45%), leukopenia

(approximately 40%), and dermatitis (approximately 25%), however all were grade one or grade two.

More than 70% of patients in the study showed objective tumor response after CCRT. Around 90% of patients underwent total mesorectal excision (surgery); and 17.6% achieved pathological complete response (pCR). 50% of patients receiving surgery in the study had good tumor regression (tumor regression grade 0 or 1 according to modified Ryan scheme).

The RP2D has been defined as 22% of tumor volume and the extension phase II is ongoing in Taiwan.

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### 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](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 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](http://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.*