



Nanobiotix announces positive first results for novel NBTXR3 in rectal cancer study at ASCO-GI 2021

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- **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 (NBTXR3), 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.

About NANOBIOTIX

Nanobiotix is a late-stage clinical biotechnology company pioneering disruptive, physics-based therapeutic approaches to revolutionize treatment

outcomes for millions of patients; supported by people committed to making a difference for humanity. The company's philosophy is rooted in the concept of pushing past the boundaries of what is known to expand possibilities for human life.

Incorporated in 2003, Nanobiotix is headquartered in Paris, France. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, Germany and Switzerland.

Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

Nanobiotix is the owner of more than 30 umbrella patents associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system. The company's resources are primarily devoted to the development of its lead product candidate— NBTXR3 —which is the product of its proprietary oncology platform and has already achieved market authorization in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on [LinkedIn](#) and [Twitter](#).

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