

NANOBIOTIX

EXPANDING LIFE

NANOBIOTIX Announces Recommended Phase 2 Dose for NBTXR3 in Pancreatic Cancer

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- Data show that radiotherapy-activated NBTXR3 was feasible and well tolerated in the complete dose escalation part of a Study 2019-1001, a phase 1 evaluation of NBTXR3 for patients with locally advanced pancreatic adenocarcinoma
- The recommended phase 2 dose for radiotherapy-activated NBTXR3 in pancreatic cancer was established at 42% of gross tumor volume and the dose expansion part of the study is ongoing in the United States
- The company expects to report safety and early efficacy data from the escalation part of the study at a medical congress in 2023

PARIS and CAMBRIDGE, Mass., Nov. 14, 2022 (GLOBE NEWSWIRE) -- [NANOBIOTIX](#) (Euronext : NANO — NASDAQ: NBTX – the “**Company**”), a late-clinical stage biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced completion of the dose escalation part of a phase 1 dose escalation and dose expansion study evaluating potential first-in-class radioenhancer NBTXR3 for patients with locally advanced (LA) or borderline resectable (BR) pancreatic cancer (PC). The phase 1 study (“Study 2019-1001”) is being conducted by The University of Texas MD Anderson Cancer Center (MD Anderson).

“The tolerable safety profile, establishment of recommended phase 2 dose, and early signals of efficacy we have observed in the dose escalation part for locally advanced patients of our phase 1 study give us confidence to now include borderline resectable patients in the expansion part,” said Leonard A. Farber, MD, Chief Clinical and Medical Affairs Officer at Nanobiotix. *“In the borderline resectable pancreatic cancer population, a positive correlation has been observed between achieving resectability through local and systemic control with preoperative therapy and potentially improving survival outcomes. Inclusion of the borderline resectable stage in the study will also expand the eligible patient population to include a larger proportion of pancreatic cancer patients, allowing for the robust evaluation of NBTXR3’s potential to have a significant impact in this recalcitrant disease.”*

Study 2019-1001 is being conducted as part of the ongoing strategic collaboration between Nanobiotix and MD Anderson. The complete dose escalation part of the study recruited 11 patients, and all patients had unresectable disease at study entry. A single intratumoral injection of NBTXR3 followed by 15 fractions of RT showed to be feasible and well-tolerated and the recommended phase 2 dose of NBTXR3 was established at 42% of gross tumor volume.

Notably, one patient on Study 2019-1001 had a partial response 9 months after RT and has had durable local control for over two years. One other patient experienced local control that allowed unresectable disease to become resectable. Negative margin surgery (“R0 surgery”) was achieved for this patient and pathological complete response was observed. The dose expansion part of the study will include more robust evaluation of patients with borderline resectable disease at study entry.

About Study 2019-1001

Pancreatic cancer (PC) is a rare, deadly disease. Given that surgery with R0 resection (i.e., macroscopically complete tumor removal with negative microscopic surgical margins) remains the only hope for long-term survival, clinical trials have investigated various neoadjuvant strategies—wherein patients receive anti-cancer drugs or radiation prior to surgery—to increase the surgery-eligible population while also increasing the R0 resection rate.

MD Anderson Study 2019-1001 is an open-label, single-arm, prospective phase I study consisting of two parts: (i) dose-escalation to determine the recommended phase 2 dose (RP2D); and (ii) expansion at RP2D.

The patient population will include adults (age \geq 18 years) with borderline resectable (BR) or locally advanced (LA) PC that are radiographically non-metastatic at screening, and that have not previously received radiation therapy or surgery for pancreatic cancer. The complete dose escalation part recruited 11 patients with unresectable LAPC and the RP2D was established at 42% of gross tumor volume. Twelve additional patients with either LAPC or BRPC will be enrolled for the RP2D expansion.

The objectives of the study are the determination of dose-limiting toxicity (DLT), the maximum tolerated dose (MTD), and the RP2D.

About NBTXR3

NBTXR3 is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles that is administered via one-time intratumoral injection and activated by radiotherapy. The product candidate’s physical mechanism of action (MoA) is designed to induce significant tumor cell death in the injected tumor when activated by radiotherapy, subsequently triggering adaptive immune response and long-term anti-cancer memory. Given the physical MoA, Nanobiotix believes that NBTXR3 could be scalable across any solid tumor that can be treated with radiotherapy and across any therapeutic combination, particularly immune checkpoint inhibitors.

NBTXR3 is being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) as the primary development pathway. The company-sponsored phase I dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy; and a phase III global registrational study was launched in 2021. In February 2020, the United States Food and Drug Administration granted regulatory Fast Track designation for the investigation of NBTXR3 activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced HNSCC who are not eligible for platinum-based chemotherapy—the same population being evaluated in the phase III study.

Nanobiotix has also prioritized an Immuno-Oncology development program—beginning with a Company-sponsored phase I clinical study evaluating NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors for patients with locoregional recurrent or recurrent/metastatic

HNSCC, or lung or liver metastases from any primary cancer eligible for anti-PD-1 therapy.

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in a strategic collaboration strategy with world class partners to expand development of the product candidate in parallel with its priority development pathways. Pursuant to this strategy, in 2019 Nanobiotix entered into a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center to sponsor several phase I and phase II studies to evaluate NBTXR3 across tumor types and therapeutic combinations.

About NANOBOTIX:

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, and Germany. Nanobiotix has been listed on Euronext: 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](#).

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," "can," "could," "estimate," "expect," "intend," "is designated to," "may," "might," "on track," "plan," "potential," "predict," "objective," "shall," "should," "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, the timing of our presentation of data, the results of our preclinical and clinical studies and their potential implications. 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 risk that subsequent studies and ongoing or future clinical trials may not generate favorable data notwithstanding positive early clinical results; the risks associated with the evolving nature of the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to it; the risk that the EIB may accelerate the loans under finance contract and its amendment upon the occurrence of customary events of default; the risk that Company may not be able to secure additional capital on attractive terms. Furthermore, many other important risks factors and uncertainties, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 8, 2022 under "Item 3.D. Risk Factors" and those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers – the AMF) on April 8, 2022, (a copy of which is available on www.nanobiotix.com), as well as those set forth in the half-year financial report filed with the AMF on September 28, 2022, 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.

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