



## **NANOBIOTIX Announces Presentation of First Data From Phase 1 Study Evaluating NBTXR3 for Patients With Locally Advanced Pancreatic Cancer**

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*Data presented at the 2023 Special Meeting on Pancreatic Cancer of the American Association for Cancer Research*

- Preliminary data show local endoscopic injection of NBTXR3 followed by radiotherapy activation remains feasible with a tolerable safety profile in 15 patients
- As of the data cutoff, in 13 patients evaluable for efficacy, the study showed an injected tumor disease control rate of 92.3% (12/13)
- Preliminary results from the ongoing study showed median overall survival of 21 months from diagnosis in the evaluable population
- These data suggest treatment feasibility and promising, durable anti-tumor efficacy of radiotherapy-activated NBTXR3 in this population and support rationale for later stage development in pancreatic cancer

PARIS and CAMBRIDGE, Mass., Sept. 28, 2023 (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 new clinical data from a Phase 1 study evaluating radiotherapy-activated NBTXR3 for patients with pancreatic ductal adenocarcinoma (PDAC). The study is being conducted as part of an ongoing collaboration between Nanobiotix and The University of Texas MD Anderson Cancer Center (MD Anderson) and results were presented at the American Association for Cancer Research (AACR) 2023 Special Conference on Pancreatic Cancer.

PDAC is an indication associated with poor prognosis and an increasing impact on cancer-related mortality worldwide. For the more than 90% of patients with locally advanced disease that is not eligible for surgery (unresectable), there are few treatment options with curative intent. As such, the 5-year overall survival rate for patients with unresectable PDAC remains less than 5%. These patients present an urgent unmet need for new treatment options that provide effective local control with tolerable safety profiles.

### **ABSTRACT #B002: Phase 1 Study of Endoscopic Ultrasound-guided NBTXR3 delivery activated by Radiotherapy for Locally Advanced or Borderline Resectable Pancreatic Cancer (LAPC or BRPC)**

Given the universal, physics-based mechanism of action of potential first-in-class radioenhancer NBTXR3, promising early signs of safety and efficacy across several other tumor indications, and the urgent need for better treatment options to control local disease in patients with pancreatic cancer, MD Anderson and Nanobiotix aligned to evaluate the potential of the radioenhancer in a Phase 1 study.

This Phase 1 study was designed with two parts:

1. The dose-finding part with 1 patient at dose level 1 (33% of gross tumor volume) and 9 patients at dose level 2 (42% of gross tumor volume)
2. The expansion part at the recommended phase 2 dose (RP2D) with 12 additional patients

NBTXR3 was administered prior to radiotherapy (RT) via an endoscopic ultrasound (EUS)-guided intratumoral injection. All patients received low-dose intensity-modulated radiation (IMRT; 45 Gy) in 15 fractions, and were followed up to one year. Importantly, all patients in the study had previously received a 4-month course of chemotherapy and showed no radiographic evidence of metastases at screening. The first patient at dose level 1 and subsequent 14 patients at dose level 2 had no injection complications. One patient at dose level 2 had 1 dose-limiting toxicity related to RT (Grade 3 elevated liver function).

As of the data cutoff, 13 patients were evaluable for efficacy. 11 patients had stable disease (SD), 1 had progressive disease in the injected lesion, and 1 had a pathological complete response after surgery. Taken together, these results represent a 92.3% local disease control rate (12/13) and a median Overall Survival of 21 months in evaluable patients. Notably, the patient who achieved pathological complete response entered the study with an unresectable tumor.

The dose-finding part of the study is complete, establishing the RP2D at 42% of gross tumor volume (GTV) and achieving the primary objective of the trial. The expansion part remains ongoing. The principal investigator concluded that these data suggest tolerable safety and promising early signs of anti-tumor efficacy. The Company believes these results support the rationale for further development of NBTXR3 in pancreatic cancer.

### **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. Its proof-of-concept was achieved in soft tissue sarcomas for which the product received a European CE mark in 2019. 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.

Radiotherapy-activated NBTXR3 is being evaluated across multiple solid tumor indications as a single agent or in combination with anti-PD-1 immune checkpoint inhibitors, including in NANORAY-312—a global, randomized Phase 3 study in locally advanced head and neck squamous cell cancers. 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 3 study.

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in a collaboration strategy 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 1 and Phase 2 studies evaluating NBTXR3 across tumor types and therapeutic combinations. In 2021, the Company announced an agreement with LianBio to expand development of NBTXR3 into Greater China and other Asian Markets, and in 2023 Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

## 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 and is listed on Euronext Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020. The Company has subsidiaries in, among other, Cambridge, Massachusetts (United States).

Nanobiotix is the owner of more than 20 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 been granted with a CE marking 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](http://www.nanobiotix.com) or follow us on [LinkedIn](#) and [Twitter](#).

## Cautionary Statement

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 "additional", "aim", "continue", "could", "drive", "enable", "expect", "further", "look forward", "may", "ongoing", "potential", "promise", "realize", "subject to", "success-based", "up to", "will", and "would" or the negative of these and similar expressions. These forward-looking statements, which are based on the management's current expectations and assumptions and on information currently available to management, include statements about the overall development of NBTXR3, including the timing and progress of clinical trials; the development of NBTXR3 pursuant to the license agreement with Janssen (the "Agreement") and the potential payments for which Nanobiotix is eligible under the Agreement; the potential for, and possible size of, the proposed equity investment by Johnson & Johnson – JJDC Inc; and the financial position of Nanobiotix. 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; the risks arising from Nanobiotix's reliance on Janssen to conduct development and commercialization activities with respect to NBTXR3, including the potential for disagreements or disputes under the Agreement; the risk that Janssen may exercise its discretion in a manner that limits the resources contributed toward the development of NBTXR3 under the Agreement or may exercise its faculty to terminate without cause the Agreement; the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data; the risk that the Company and EIB will not reach definitive agreement with respect to the removal of the cash-covenant, and the risk that the Company may not be able to secure additional capital on attractive terms, if at all. 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 24, 2023 under "Item 3.D. Risk Factors", 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 24, 2023, and those set forth in the half-year report filed with SEC on form 6-K and with AMF on September 26, 2023 (copies of which are available on [www.nanobiotix.com](http://www.nanobiotix.com)), 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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## Attachment

- [2023-09-28 -- NBTX -- Ph1 NBTXR3 Data @ AACR -- FINAL.pdf](#)

