Nanobiotix Establishes Recommended Dose for Planned Registrational Study Evaluating NBTXR3 Plus Anti-PD-1 for Patients With Metastatic Head and Neck Cancer Resistant to Prior Immunotherapy

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- **Recommended phase 2 dose established at 33% of gross tumor volume in all three cohorts from the complete escalation part of Study 1100**
- **Updated clinical data from Study 1100 expected in Q4 2022**
- **Submission of protocol to United States Food and Drug Administration for Phase 3 clinical trial evaluating NBTXR3 in combination with anti-PD-1 for patients with head and neck cancer expected in Q1 2023**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 21, 2022-- Regulatory News:

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 determination of the recommended phase 2 dose (RP2D) of NBTXR3 in combination with pembrolizumab or nivolumab for the treatment of patients suffering from inoperable locoregional recurrent (LRR) or recurrent and metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) that is resistant to prior immunotherapy. RP2Ds were determined for NBTXR3 plus pembrolizumab or nivolumab for patients with LRR or R/M HNSCC that has not received prior immunotherapy, lung metastases (mets) from any primary tumor, or liver mets from any primary tumor as well.

The combined dose escalation and dose expansion parts of Study 1100 are expected to enroll up to 141 patients. The complete dose escalation part enrolled 29 patients in three cohorts: (i) head and neck lesions from LRR or R/M HNSCC eligible for anti-PD-1 therapy; (ii) lung mets from any primary cancer eligible for anti-PD-1 therapy; and (iii) liver mets from any primary cancer eligible for anti-PD-1 therapy. Study participants received a one-time intratumoral injection of NBTXR3 prior to their first radiotherapy session. They then received radiotherapy, followed by anti-PD-1. Based on the study's results, the RP2D for all three cohorts was determined to be 33% of gross tumor volume.

Nanobiotix aims to deliver an industry-leading head and neck cancer treatment franchise powered by NBTXR3, and to replicate that approach across other solid tumor indications. Pursuant to this strategy, the Company has amended the ongoing expansion phase of Study 1100 to further strengthen the rationale behind a registrational protocol evaluating NBTXR3 plus anti-PD-1 for patients with R/M HNSCC that is resistant to prior immunotherapy.

The amended dose expansion part of study 1100 also has three cohorts, however the cohorts have been re-designed to further explore NBTXR3 plus anti-PD-1 in several immunotherapy-eligible indications, with a particular focus on the treatment of patients with LRR or R/M HNSCC primary lesions that are either naïve or resistant to prior immunotherapy. The expansion part cohorts are as follows: (i) LRR or R/M HNSCC that is resistant to prior immunotherapy; (ii) LRR or R/M HNSCC that has not received prior immunotherapy; (iii) lung, liver, or soft tissue mets from inoperable NSCLC, malignant melanoma, hepatocellular carcinoma, renal cell carcinoma (RCC), urothelial cancer, cervical cancer, or triple negative breast cancer (TNBC) primary tumors.

The Company expects to provide updated clinical data from Study 1100 in Q4 2022. The registrational phase 3 protocol submission is expected in Q1 2023, followed by modification of the study design.

About NBTXR3

NBTXR3 is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles 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 solid tumors that can be treated with radiotherapy and across different therapeutic combinations.

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 is leveraging its proprietary nanoparticle platform, including its lead product candidate, radiotherapy activated NBTXR3, to develop a pipeline of therapeutic options designed to enhance local and systemic control of solid tumors with an initial focus on the treatment of head and neck cancers.

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," "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, 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 and 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 Company and EIB will not reach definitive agreement with respect to the restructuring of the loan; 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, 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 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), 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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