



NANOBIOTIX and LianBio Announce First Patient Enrolled in Asia in Phase 3 NANORAY-312 Trial Evaluating NBTXR3 for the Treatment of Head and Neck Cancer

September 7, 2022 8:15 PM EDT

- **Regional activation for Nanobiotix pivotal Phase 3 trial in head and neck cancer proceeds as planned with first patient enrolled in Asia by partner LianBio**
- **The collaboration continues to build momentum behind LianBio's leadership in Asia while Nanobiotix remains focused on enrollment globally**

PARIS & CAMBRIDGE, Mass. & SHANGHAI, China & PRINCETON, N.J.--(BUSINESS WIRE)--Sep. 7, 2022-- Regulatory News:

NANOBIOTIX (Euronext: NANO – Nasdaq: NBTX), a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, and **LianBio** (Nasdaq: LIAN), a biotechnology company dedicated to bringing paradigm-shifting medicines to patients in China and major Asian markets today announced randomization of the first patient in Asia in NANORAY-312, a global Phase 3 registrational trial evaluating NBTXR3 for the treatment of elderly patients with locally advanced head and neck squamous cell carcinoma ("LA-HNSCC") who are ineligible for platinum-based chemotherapy.

"We believe NBTXR3 has demonstrated the potential to improve treatment outcomes in multiple solid tumor indications, including in Study 102, the Nanobiotix Phase 1 trial evaluating the product candidate for the treatment of elderly patients with locally advanced head and neck squamous cell carcinoma," said Yizhe Wang, Ph.D., Chief Executive Officer, LianBio. "We look forward to working with our clinical partners at sites across Greater China and South Korea to evaluate NBTXR3 in this difficult-to-treat patient population. With radiotherapy usage on the rise in Asia, we believe NBTXR3 may become an important part of the treatment landscape for patients with cancer in the region."

NANORAY-312 is a global, two-arm, randomized, Investigator's Choice Phase 3 registrational study that is designed to investigate the efficacy and safety of radiotherapy-activated NBTXR3 with or without cetuximab versus radiotherapy with or without cetuximab in high-risk, chemotherapy-ineligible elderly patients with LA-HNSCC. Eligible participants for NANORAY-312 will be treated with NBTXR3 at a 1:1 ratio after an Investigator's Choice of radiotherapy alone or radiotherapy in combination with cetuximab. This pivotal trial is expected to enroll 500 patients globally, with approximately 100 patients expected to be enrolled in LianBio's licensed territories participating in the study.

NANORAY-312 builds on Nanobiotix Study 102, a Phase 1 trial evaluating safety and early signs of efficacy for radiotherapy-activated NBTXR3 in high-risk elderly LA-HNSCC patients who are chemotherapy-ineligible and intolerant to cetuximab. To date, Study 102 has demonstrated median overall survival of 17.9 months in the all-treated population (n=56) and 23.0 months in the evaluable patients (n=44).

LianBio holds exclusive rights to develop and commercialize NBTXR3 in Greater China, South Korea, Singapore and Thailand.

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. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of radiotherapy-activated NBTXR3 in the NANORAY-312 population.

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. Nanobiotix 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](#)

About LianBio

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to patients in China and other Asian markets. Through partnerships with highly innovative biopharmaceutical companies around the world, LianBio is advancing a diversified portfolio of clinically validated product candidates with the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications. LianBio is establishing an international infrastructure to position itself as a partner of choice with a platform to provide access to China and other Asian markets. For more information, please visit www.lianbio.com.

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 Nanobiotix and LianBio's current expectations and assumptions and on information currently available to management, include statements about

NBTXR3's potential as a clinical candidate, including: (i) its potential role as part of the treatment landscape for cancer patients; (ii) the timing and progress of clinical trials; (iii) the expected timing of Nanobiotix or LianBio's presentation of data; (iv) the results of Nanobiotix's preclinical or clinical studies and their potential implications; (v) the potential for results from NANORAY-312 to support regulatory approval in LianBio's licensed territories in Asia; and (vi) the development of NBTXR3 in Asian markets under Nanobiotix's license agreement with LianBio. Such forward-looking statements are made in light of information currently available to Nanobiotix and LianBio and are based on assumptions that Nanobiotix and LianBio consider to be reasonable. However, these forward-looking statements are subject to numerous risks and uncertainties, including: (i) with respect to the risk that subsequent studies and clinical trials may not generate favorable data notwithstanding positive preclinical results; and (ii) the risks associated with the evolving nature, duration, and severity of the COVID-19 pandemic along with governmental and regulatory measures implemented in response. Furthermore, many other important factors, including: (i) those described in Nanobiotix's 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"; (ii) those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des marchés financiers) under number D.21-0272 on April 8, 2022 (a copy of which is available on www.nanobiotix.com); and (iii) in LianBio's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings with the SEC, as well as other known and unknown risks and uncertainties, may adversely affect such forward-looking statements and cause actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, neither Nanobiotix nor LianBio assume any 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220907006108/en/): <https://www.businesswire.com/news/home/20220907006108/en/>

Nanobiotix

Nanobiotix Communications

Brandon Owens

VP, Communications

+1 (617) 852-4835

contact@nanobiotix.com

Nanobiotix Investor Relations

Kate McNeil

SVP, Investor Relations

+1 (609) 678-7388

investors@nanobiotix.com

Nanobiotix Media Relations

France – Ulysse Communication

Pierre-Louis Germain

+ 33 (0) 6 64 79 97 51

plgermain@ulyse-communication.com

Global – LifeSci Advisors

Ligia Vela-Reid

+44 (0) 7413825310

Lvela-reid@lifesciadvisors.com

LianBio

LianBio Communications and Investor Relations

Elizabeth Anderson

VP, Communications & Investor Relations

+1 (646) 655-8390

elizabeth.anderson@lianbio.com

LianBio Media Relations

Evoke Canale

Katherine Smith

+1 (619) 849-5378

katherine.smith@evokegroup.com

Source: NANBIOTIX