

LianBio Enters into Agreement Assigning its Rights for NBTXR3 in China and Other Asian Markets

December 26, 2023

SHANGHAI, China and PRINCETON, N.J., Dec. 26, 2023 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced that the company has entered into an agreement with Janssen Pharmaceutica NV ("Janssen"), a Johnson & Johnson company, whereby Lian has assigned to Janssen LianBio's exclusive rights to develop and commercialize NBTXR3, an investigational, potential first-in-class radioenhancer, in China, South Korea, Singapore and Thailand.

Under the terms of the agreement, LianBio will receive a one-time payment of \$25 million. In addition, LianBio is eligible to receive a sales milestone payment of \$5 million. Following the deal close, LianBio will support the transition of the asset to Janssen for a period no longer than six months.

In July 2023, Nanobiotix granted Janssen a worldwide exclusive license, excepting territories previously licensed to LianBio, for the co-development and commercialization of NBTXR3.

"NBTXR3 has demonstrated the potential to improve treatment outcomes across a number of high need solid tumor indications," said Konstantin Poukalov, Executive Chairman of the LianBio Board of Directors. "We believe this transaction will build upon the strong foundation LianBio has built for NBTXR3 in Asia."

"LianBio has served as an important partner in the ongoing pivotal NANORAY-312 clinical trial of NBTXR3 in head and neck squamous cell carcinoma," said Laurent Levy, co-founder and chairman of the executive board at Nanobiotix. "We look forward to continuing to advance the clinical development of NBTXR3 in Asia and bringing new treatment options to those in need around the globe."

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, NBTXR3 could potentially 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, with a Phase 3 global registrational study ongoing called NANORAY-312. The global study is investigating 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 locally advanced head and neck squamous cell carcinoma. 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. More information about NANORAY-312 can be found on ClinicalTrials.gov (NCT04892173). 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.

LianBio licensed rights from Nanobiotix in May 2021 for the development and commercialization of NBTXR3 in Mainland China, Hong Kong, Macau, Taiwan, Thailand, South Korea, and Singapore.

About LianBio

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to historically underserved 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, and inflammatory disease. LianBio is establishing an international infrastructure to position the company 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.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements. The words "potential", "continue," "will," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include, but are not limited to, statements regarding the payments LianBio will receive pursuant to the agreement with Janssen, LianBio's plans to support the transition of assets to Janssen and Janssen's ability to expedite the NANORAY-312 Phase 3 trial. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: LianBio's ability to successfully initiate and conduct its planned clinical trials and complete such clinical trials and obtain results on its expected timelines, or at all; LianBio's plans to leverage data generated in its partners' global registrational trials and clinical development programs to obtain regulatory approval and maximize patient reach for its product candidates; LianBio's ability to identify new product candidates and successfully acquire such product candidates from third parties; competition from other biotechnology and pharmaceutical companies; general market conditions; the impact of changing laws and regulations and those risks and uncertainties described in LianBio's filings with the U.S. Securities and Exchange Commission (SEC), including LianBio's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the SEC. Any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon this information as current or accurate after its publication date.

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