LianBio Partner NANOBIOTIX Enters into License Agreement with Janssen for Radioenhancer NBTXR3, with LianBio Retaining Development and Commercialization Rights in Greater China, South Korea, Singapore and Thailand

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SHANGHAI, China and PRINCETON, N.J., July 18, 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 partner Nanobiotix has entered into a license agreement with Janssen Pharmaceutica NV ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the investigational, potential first-in-class radioenhancer NBTXR3.

Nanobiotix will grant Janssen a worldwide license for the co-development and commercialization of NBTXR3. The license is exclusive, excepting territories previously licensed to LianBio.

"Data generated to date suggest NBTXR3 has potential to address the treatment limitations of standard of care radiotherapy across multiple solid tumor indications," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "We believe Nanobiotix's collaboration with Janssen will provide additional expertise and financial resources to broadly develop NBTXR3 in areas of high unmet medical need."

Details and financial terms of the Nanobiotix and Janssen collaboration are available on the investor section of the Nanobiotix website.

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. LianBio and Nanobiotix are currently enrolling patients in NANORAY-312, a global Phase 3 trial 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 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. This pivotal trial is expected to enroll 500 patients globally, with approximately 100 patients in LianBio's licensed territories expected to participate in the study. More information about NANORAY-312 can be found on ClinicalTrials.gov (NCT04892173).

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. 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.

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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 "expect," "believe," "potential," "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 LianBio's beliefs regarding the potential of NBTXR3 to address the treatment limitations of standard of care radiotherapy across multiple solid tumor indications and the potential for the Nanobiotix and Janssen collaboration to provide additional expertise and financial resources to broadly develop NBTXR3 in areas of high unmet medical need, and LianBio's and Nanobiotix's plans for 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 statements contained in this press release speak only as of the date hereof, and LianBio specifically disclaims any obligation to update 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.

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.

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