Y-mAbs Announces First Patient Dosed in Phase 1 Clinical Trial Evaluating CD38-SADA Pre-targeted Radioimmunotherapy in Relapsed/Refractory Non-Hodgkin Lymphoma

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NEW YORK, April 25, 2025 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel radioimmunotherapy and antibody-based therapeutic products for the treatment of cancer, today announced that the first patient has been administered both the first protein dose and the ^{177}Lu-DOTA imaging dose in its Phase 1 clinical trial evaluating the Company's Self-Assembly and Disassembly ("SADA") Pre-targeted Radioimmunotherapy ("PRIT") platform for the treatment of patients with relapsed or refractory non-Hodgkin Lymphoma (r/r NHL). This Phase 1 trial (Trial 1201) is a dose-escalation, open-label, single-arm, multi-center trial investigating the safety and tolerability of the CD38-SADA: ^{177}Lu-DOTA Drug Complex.

Trial 1201 is designed to investigate the pre-targeted delivery of the CD38-SADA protein that binds with high affinity to lymphoma cells, followed by the administration of a radioactive ^{177}Lu-DOTA payload to selectively target the tumor-bound CD38-SADA molecules while minimizing radiation to normal tissues. Part A of the trial is CD38-SADA dose escalation with fixed ^{177}Lu-DOTA payload doses to explore the optimal CD38-SADA protein dose and interval between the SADA protein administration and the payload. The primary endpoints of Part A include tumor imaging and occurrence of dose limiting toxicities in the dose limiting toxicities (DLT) evaluation period.

"We are excited to announce the dosing of the first patient in Trial 1201 in patients with relapsed or refractory non-Hodgkin Lymphoma, our second clinical program evaluating the SADA PRIT platform and our first in hematological malignancies," said Norman LaFrance, M.D., Chief Development and Medical Officer. "Relapsed and refractory NHL presents significant challenges for patients facing limited treatment options and a more aggressive disease course. We believe that our innovative approach to pre-targeted radioimmunotherapy has the potential to significantly improve outcomes in this high-risk population."

In addition to CD38-SADA, the modular design of the SADA PRIT platform has facilitated the clinical development of other bispecific fusion proteins, including GD2-SADA, now in clinical development for the treatment of GD2-expressing tumors.

Researchers at MSK, including Dr. Nai-Kong Cheung, developed the SADA technology for radioimmunotherapy, which is exclusively licensed by MSK to Y-mAbs. Dr. Cheung has intellectual property rights and interests in the technology, and as a result of this licensing arrangement, MSK has institutional financial interests in the technology.

About Y-mAbs
Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, radioimmunotherapy and antibody-based therapeutic cancer products. The Company's technologies include its investigational Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy Platform ("PRIT"), and bispecific antibodies generated using the Y-BiClone platform. The Company's broad and advanced product pipeline includes the anti-GD2 therapy DANYELZA® (naxitamab-gqgk), the first FDA-approved treatment for patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow after a partial response, minor response, or stable disease to prior therapy.

About CD38-SADA PRIT
CD38-SADA is a bispecific fusion protein that tightly binds to the CD38 glycoprotein and to ^{177}Lu-tetraxetan (^{177}Lu -DOTA), a "caged" radionuclide. In the first step of pre-targeted radioimmunotherapy, non-radiolabeled CD38-SADA tetramers are infused and bind to CD38-expressing lymphoma cells, and unbound CD38-SADA protein disassembles into low molecular weight monomers that are removed by the kidney. The second infusion delivers the "radioactive payload," which binds directly to CD38-SADA on tumor cells for localized irradiation. CD38-SADA PRIT with ^{177}Lu-DOTA has demonstrated robust anti-tumor efficacy in preclinical studies and is currently being investigated in adults with relapsed, progressive, or refractory NHL (CD38-expressing B-cell, T-cell, and natural killer cell lymphomas) after at least 2 prior lines of therapy (NCT05994157).

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" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about our business model, including financial outlook for 2024 and beyond. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," "guidance," "goal," "objective," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company's business is subject to risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and the Company's Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2024, and September 30, 2024, and future filings and reports by the Company. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contact:

Courtney Dugan
VP, Head of Investor Relations
cdu@ymabs.com

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