Y-mAbs Presents Translational Pharmacokinetics of CD38-SADA from Pretargeted RIT Platform at 2025 American Association for Cancer Research (AACR) Annual Meeting

April 27, 2025

NEW YORK, April 27, 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 the presentation of preclinical and translational pharmacokinetics (PK) data of CD38-SADA in a poster at the 2025 American Association of Cancer Research (AACR) Annual Meeting being held on April 25-30, 2025 in Chicago, IL.

The poster titled "*Preclinical and translational pharmacokinetic (PK) modeling of the self-assembling and disassembling (SADA) bispecific fusion protein CD38-SADA for first-in-human (FIH) pretargeted radioimmunotherapy (PRIT)"* characterizes the plasma concentrations of CD38-SADA in animal models over time and a range of doses. Utilizing *in vitro* binding kinetic parameters and PK data generated from three studies in mice, the study characterized the concentration- and time-dependent equilibrium between CD38-SADA tetramers and monomers.

Previous preclinical reports have shown that the non-radiolabeled CD38-SADA tetramers bind with high-avidity to tumors during the first "pre-targeting" infusion. Building on these data, the preclinical PK model tracked the plasma levels of the CD38-SADA protein. Importantly, the model's estimated linear clearance of low molecular weight CD38-SADA monomers was 20-times faster than the CD38-SADA tetramers, providing additional evidence for their significantly reduced levels before delivery of the radioactive payload in the second infusion. This is an important consideration in evaluating the tumor-to-normal tissue absorbed dose ratios of Lutetium 177 (Lu 177)-DOTA, the chelated radionuclide administered in Trial 1201.

"Our preclinical models have provided important insights into the circulating levels of CD38-SADA protein *in vivo*," said Brian Santich, Ph.D., lead author and Vice President of Research. "Using these data, we conducted a series of appropriately scaled human PK simulations which informed the design and initial dosing regimen of our first-in-human Phase 1 Trial 1201 in patients with r/r NHL."

"With the recent dosing of our first patient in Trial 1201, we look forward to reviewing initial patient data as our CD38-SADA program advances," said Norman LaFrance, M.D., co-author and Chief Medical and Development Officer.

The abstract details are below:

Abstract Title: *"Preclinical and translational pharmacokinetic (PK) modeling of the self-assembling and disassembling (SADA) bispecific fusion protein CD38-SADA for first-in-human (FIH) pretargeted radioimmunotherapy (PRIT)"*
Format: Poster Presentation, ID: 566
Location: Poster Section 25
Date and Time: Sunday, April 27, 2025, 2:00 p.m. to 5:00 p.m. CT

Researchers at Memorial Sloan Kettering Cancer Center (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, including estimated operating expenses, use of cash and cash equivalents and DANYELZA product revenue and sufficiency of cash resources and related assumptions; expectations with respect to the Company's future financial performance; implied and express statements regarding the future of the Company's business, including with respect to expansion and its goals; expectations with respect to the Company's plans and strategies, development, regulatory, commercialization and product distribution plans, including the timing thereof; expectations with respect to the Company's products and product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA PRIT technology and potential benefits and applications thereof; expectations relating to key anticipated development milestones, including potential expansion and advancement of commercialization and

development efforts, including potential indications, applications and geographies, and the timing thereof; expectations with respect to current and future clinical and pre-clinical studies and the Company's research and development programs, including with respect to timing and results; expectations regarding collaborations or strategic partnerships and the potential benefits thereof; and other statements that are not historical facts. 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. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with the Company's financial condition and need for additional capital; the risks that actual results of the Company's restructuring plan and revised business plan will not be as expected; risks associated with the Company's development work; cost and success of the Company's product development activities and clinical trials; the risks of delay in the timing of the Company's or its partners' regulatory submissions or failure to receive approval of its drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of product candidates; development of sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for products; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture as well as regulatory submissions; the Company's ability to enter into new partnerships or to recognize the anticipated benefits from its existing partnerships; risks related to government regulation; risks related to market approval, risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's common stock, risks associated with macroeconomic conditions, including the conflict between Russia and Ukraine and sanctions related thereto, the state of war between Israel and Hamas and the related risk of a larger regional conflict, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; and other 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.

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Source: Y-mAbs Therapeutics, Inc.