Y-mAbs Presents Translational Pharmacokinetics of GD2-SADA from Pretargeted RIT Platform at the SNMMI Mid-Winter and ACNM Annual Meeting

January 31, 2025

NEW YORK, Jan. 31, 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 GD2-SADA in a poster at the Society of Nuclear Medicine & Molecular Imaging (SNMMI) Mid-Winter and American College of Nuclear Medicine (ACNM) Annual Meeting being held on January 30 to February 1, 2025 in Anaheim, California.

The poster titled "*Preclinical and Translational Pharmacokinetics of GD2-SADA, a Self-Assembling and Disassembling (SADA) Bispecific Fusion Protein for Pretargeted Radioimmunotherapy (PRIT)"* characterizes the plasma levels of GD2-SADA in animal models over time and a range of doses, while also presenting the concentration- and time-dependent equilibrium between GD2-SADA tetramers and monomers *in vitro*. Incorporated within translational PK simulations, the data have provided important insights into GD2-SADA tumor exposure and plasma elimination, key parameters for minimizing systemic exposure to ^{177}Lutetium-DOTA.

"The human PK model of GD2-SADA informed the design and initial dosing regimen of our ongoing first-in-human (FIH) Phase 1 Trial (Trial 1001)," said Norman LaFrance, M.D., Chief Development Officer. "We are looking forward to refining this model with patient-level data obtained from Trial 1001, while also advancing similar work with other planned SADA PRIT trials."

The abstract details are below:

Abstract Title: "Preclinical and translational pharmacokinetics of GD2-SADA, a self-assembling and disassembling (SADA) bispecific fusion protein for pretargeted radioimmunotherapy (PRIT)"
Format: Poster Presentation, ID: A2578
Date and Time: Friday, January 31, 2025 at 7:00 a.m. to 12:15 p.m. PT

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 GD2-SADA PRIT
GD2-SADA is a bispecific fusion protein that tightly binds to the glycolipid GD2 and Lutetium 177 (Lu ^{177})-DOTA, a chelated or "caged" radionuclide. In the first step of pre-targeted radiotherapy, non-radiolabeled GD2-SADA tetramers are infused and bind to GD2-expressing solid tumors, while unbound GD2-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 GD2-SADA on tumor cells for localized irradiation. GD2- SADA PRIT with ^{177}Lutetium-DOTA has demonstrated robust anti-tumor efficacy in preclinical studies and is currently being investigated in adults and adolescents with GD2-expressing solid tumors in Trial 1001 (NCT05130255).

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, 2023, 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.