Y-mAbs Presents SADA Platform Preclinical Data and Trial in Progress Posters at the 2024 American Society Hematology (ASH) Annual Meeting

December 7, 2024

NEW YORK, Dec. 07, 2024 (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 CD38-SADA in Non-Hodgkin Lymphoma (NHL) preclinical data and trial in progress posters at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition being held on December 7 –10, 2024, in San Diego, California.

A poster titled "*CD38-SADA, a **S**elf-**A**ssembling and **D**is-**A**ssembling Bispecific Fusion Protein for Two-Step Pretargeted Radioimmunotherapy of Non-Hodgkin Lymphoma*" characterizes the selective binding of CD38-SADA to DOTA-chelated lanthanide metals and high-avidity binding to CD38, a tumor specific antigen overexpressed across a range of lymphoma cells. Data from this poster demonstrate anti-tumor efficacy of CD38-SADA when used with Lutetium 177 (Lu^{177})-DOTA in a two-step approach to pre-targeted radioimmunotherapy ("PRIT"). Tumor responses in a xenograft mouse model were rapid and dose-dependent, further supporting the clinical development of CD38-SADA PRIT in patients with CD38-positive lymphoid malignancies.

"This preclinical analysis provides important insights into the unique pharmacology of CD38-SADA and its therapeutic potential for NHL," said Brian H. Santich, Ph.D., the lead author and co-inventor of the SADA PRIT technology platform. "The anti-tumor efficacy positively correlated with increasing doses of Lu^{177}-DOTA and CD38-SADA, which informed the study design and initial dosing regimen of our Trial 1201 in patients with NHL."

In addition, Y-mAbs presents a trial-in-progress poster from its ongoing Phase 1 (Trial 1201) clinical study evaluating the safety and tolerability of CD38-SADA PRIT with Lu^{177}-DOTA in adults with relapsed or refractory NHL. Trial 1201 is a first-in-human, dose-escalation, open-label, multicenter study composed of two parts. Part A includes dose escalation of the CD38-SADA bispecific fusion protein to define the optimal safe dose of the CD38-SADA protein, the administration interval between CD38-SADA and Lu^{177}-DOTA, and the Lu^{177}-DOTA dose for tumor imaging. In Part B, dose escalation of Lu^{177}-DOTA will establish the optimal therapeutic dose of the radioactive payload. For each part, the escalation is based on a 3+3 trial design of 4 planned dose levels.

"We are pleased to share the details of this Phase 1 clinical trial, which is investigating a potentially transformative approach to pre-targeted radioimmunotherapy for patients with relapsed and refractory NHL," said Vignesh Rajah, MBBS, DCH, MRCP (UK), Chief Medical Officer. "This is our second clinical program evaluating the SADA PRIT technology platform and our first in hematological malignancies."

The abstract details are below:

Abstract Title: "CD38-SADA, a Self-Assembling and Dis-Assembling Bispecific Fusion Protein for Two-Step Pretargeted Radioimmunotherapy of Non-Hodgkin Lymphoma"
Format: Poster Presentation, ID: 1599
Date and Time: Saturday, December 7, 2024, 5:30 PM-7:30 PM

Abstract Title: "CD38-SADA Pretargeted Radioimmunotherapy (PRIT) with Lutetium 177 (Lu177)-DOTA in Adult Patients with Relapsed or Refractory Non-Hodgkin Lymphoma: A First-in-Human Phase 1 Trial"
Format: Poster Presentation, ID: 4434.1
Date and Time: Monday, December 9, 2024, 6:00 PM-8:00 PM

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 antigen and to select radionuclides chelated to tetraxetan (or "DOTA"). CD38-SADA contains a p53-derived domain that drives the self-assembly of CD38-SADA tetramers, which possess four distinct binding sites for CD38. In the first step of pre-targeted radiotherapy, non-radiolabeled-CD38-SADA tetramers are infused and bind with high avidity to CD38-positive tumors, while unbound CD38-SADA disassembles into low molecular weight monomers that are removed by the kidney. The second infusion delivers the "radioactive payload," which binds to the CD38-SADA on tumor cells for localized irradiation. CD38- SADA PRIT with Lutetium 177 (Lu 177)-DOTA is now under clinical investigation in Trial 1201 (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, 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.