Y-mAbs Presents GD2-SADA PRIT Trial in Progress Poster at the Advances in Neuroblastoma Research Meeting

May 26, 2025

PRINCETON, N.J., May 26, 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 GD2-SADA in recurrent or refractory metastatic solid tumors known to express GD2 in a trial in progress poster at the Advances in Neuroblastoma Research Meeting ("ANR") being held on May 25-28, 2025 in Washington, D.C.

The trial in progress poster titled "*A phase 1 trial of pretargeted radioimmunotherapy with GD2-SADA: ^{177}Lu-DOTA in patients with high-risk neuroblastoma and other GD2+ solid tumors*" provides an overview of Trial 1001 (NCT05130255), a first-in-human, dose-escalation, single-arm, open-label, nonrandomized, multicenter Phase 1 clinical trial evaluating the safety and tolerability of GD2-SADA Pretargeted Radioimmunotherapy ("GD2-SADA PRIT") with Lutetium 177 DOTA (^{177}Lu-DOTA) in adult and adolescent patients (≥ 16 years of age and older) with recurrent or refractory metastatic GD2-expressing solid tumors, including high-risk neuroblastoma ("HR NB"), small cell lung cancer, sarcoma, and melanoma. Part A of the trial includes dose escalation of GD2-SADA protein to define the optimal safe dose of this self-assembling and disassembling protein and will also evaluate the administration interval between GD2-SADA and ^{177}Lu-DOTA.

"We are pleased to present data from our ongoing Trial 1001 in patients with high-risk neuroblastoma and other GD2-positive tumors," said Norman LaFrance, M.D., Chief Medical and Development Officer. "We have completed Part A and we look forward to providing the initial data readout during our virtual Radiopharmaceutical R&D update on May 28th."

The abstract details are below:

Abstract Title: "A phase 1 trial of pretargeted radioimmunotherapy with GD2-SADA: ^{177}Lu-DOTA in patients with high-risk neuroblastoma and other GD2+ solid tumors"
Format: Poster Presentation, Poster Session Group B, Poster # 246
Date and Time: Monday, May 26, 2025 at 4:40 p.m. – 5:10 p.m. ET

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. 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 tumor-associated antigen GD2 and Lutetium 177 DOTA (^{177}Lu-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-positive solid tumors, and 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).

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.

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 2025 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, 2025, 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.