



Y-mAbs Announces Publication of Preclinical GD2-SADA Data at 2024 ASCO Annual Meeting

June 01, 2024

NEW YORK, June 01, 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 publication of preclinical GD2-SADA data at the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting, taking place May 31 through June 4, 2024, in Chicago, IL.

The published abstract titled "Preclinical characterization of pretargeted radioimmunotherapy with GD2-SADA, a self-assembling and disassembling bispecific fusion protein" characterizes the binding properties of GD2-SADA across several GD2-expressing cell lines and lanthanide metal-DOTA complexes, while also demonstrating its anti-tumor efficacy when used with Lutetium 177 (Lu177)-DOTA in a two-step approach to pretargeted radioimmunotherapy ("PRIT").

In this analysis, GD2-SADA showed tight binding to cell lines expressing GD2, a glycolipid implicated in the malignant transformation of multiple solid tumors. GD2-SADA binding was significantly improved by a p53-derived domain that drives the self-assembly and disassembly ("SADA") of GD2-SADA tetramers, which possess four distinct GD2-binding domains that cumulatively enhance binding. Previous studies have shown that the unbound GD2-SADA protein disassembles over time, facilitating clearance by the kidneys.

"We believe that these data further validate GD2-SADA's promise as a novel targeted radioimmunotherapy and support the continued advancement of our SADA PRIT technology platform and clinical programs," said Vignesh Rajah, MBBS, DCH, MRCP (UK), Chief Medical Officer.

The analysis further demonstrated high-affinity binding of GD2-SADA to DOTA complexes chelated with lutetium and lanthanum, among other lanthanide metals. By contrast, GD2-SADA showed negligible binding to trace metal-DOTA complexes or empty DOTA, an important consideration for the targeted delivery of the radioactive payload in patients.

"We are especially encouraged by the selective binding of GD2-SADA to lanthanide metal-DOTA complexes with current and emerging applications in the diagnosis and targeted treatment of solid tumors," said Brian H. Santich, Ph.D., the lead author and co-inventor of the SADA PRIT technology platform.

Taken together, the binding properties of the GD2-SADA protein provide a pharmacological basis for the robust and dose-responsive anti-tumor effects of GD2-SADA Lu177 PRIT *in vivo*, also presented in this seminal research. These findings have paved the way for the clinical development of GD2-SADA PRIT in adults and adolescents with GD2-positive tumors ([NCT05130255](#)).

Y-mAbs will be available for comment at booth #35151 on the Exhibition Floor of McCormick Place.

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-gqqgk), 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.

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 2023 and beyond, including estimated operating expenses, cash burn and DANYELZA product revenue and sufficiency of cash resources and related assumptions; implied and express statements regarding the future of the Company's business, including with respect to expansion and its goals; the Company's plans and strategies, development, commercialization and product distribution plans, including potential partnerships; 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 Technology and potential benefits and applications thereof; statements with respect to DANYELZA as a growing commercial product and SADA as a differentiated radioimmunotherapy platform positioning the Company on a path to potentially transform the treatment paradigm for a variety of cancers and improve patients' lives; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA development efforts and the SADA Technology, including potential indications and applications, 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 related to the timing of the initiation and completion of regulatory submissions; additional product candidates and technologies; expectations regarding collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of cash and cash equivalents, and the need for, timing and amount of any future financing transaction; expectations with respect to the Company's future financial performance; 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," 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 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; the risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; the Company's inability to enter into partnerships; the 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, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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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