Y-mAbs Announces New Interim Analysis of Phase 2 Data for Naxitamab 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 new interim data from the Phase 2 Trial 201 of naxitamab in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF") in patients with relapsed or refractory high-risk neuroblastoma with residual disease limited to bone and/or bone marrow. The results are summarized in poster presentations scheduled to be presented today, June 1, 2024, at the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, IL.

Improved patient outcomes with extended naxitamab therapy: A poster titled "Patterns of improvement following initial response in patients treated with naxitamab for relapsed/refractory high-risk neuroblastoma" (poster #10033) demonstrates that continued treatment with naxitamab can further reduce disease following the initial response to naxitamab therapy. The Trial 201 prespecified interim analysis achieved a 50% overall response rate ("ORR") in 26 out of 52 patients. Nearly a quarter of patients achieved their first complete response ("CR") or partial response ("PR") after three or more cycles of naxitamab therapy. Among these patients, most had initial stable disease within specific bone or bone marrow compartments prior to achieving a CR or PR. These results support the rationale for extended naxitamab therapy in patients who do not achieve a CR or PR at first assessment.

Evolution of adverse events over the course of treatment: A poster titled "Naxitamab-related adverse events within and across treatment cycles in patients with relapsed/refractory high-risk neuroblastoma" (poster #10032) demonstrates the frequency and patterns of adverse events ("AEs") based on the interim analysis of Trial 201. In this analysis, 81% of naxitamab-related AEs were Grade 1 or 2, while Grade ≥3 AEs reported in ≥10% of patients included hypotension (60% of patients), pain (58%), urticaria (19%), bronchospasm (18%), and abdominal pain (16%). None resulted in treatment discontinuation. Notably, the frequency of naxitamab-related pain Grade 3 AEs decreased from the first cycle (53%) to the second (37%), generally stabilizing thereafter, with frequencies consistent across infusions. Similarly, the frequency of hypotension showed marked reductions across cycles and infusions.

"We are encouraged to see that some patients who did not demonstrate an objective response after initial assessment went on to achieve a complete or partial response after continued naxitamab treatment. In addition, these data provide a practical understanding of the temporal patterns of treatment-related adverse events," said Vignesh Rajah, MBBS, DCH, MRCP (UK), Chief Medical Officer.

In addition, Dr. Jaume Mora and researchers from the Sant Joan de Déu Barcelona Children's Hospital in Spain will present results from an independent retrospective analysis of patients treated with naxitamab in combination with chemotherapeutics in a poster titled "Naxitamab chemo-immunotherapy regimens other than with irinotecan/temozolomide for patients with relapsed/refractory high-risk neuroblastoma" (poster #10037). In this study, 29 patients with mostly chemo-immunotherapy refractory disease received compassionate use of naxitamab plus sargramostim in combination with alternative chemotherapeutics. Importantly, prior sensitivity to chemo-immunotherapy predicted better responses with the new combinations. The safety profiles of the alternative naxitamab chemo-immunotherapy regimens were considered manageable.

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

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed DANYELZA® (naxitamab-gqgk), which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests in the compound and Y-mAbs.

About DANYELZA® (naxitamab-gqgk)
DANYELZA® (naxitamab-gqgk) is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. This indication was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory trial. DANYELZA® includes a Boxed Warning for serious infusion-related reactions, such as cardiac arrest and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. See full Prescribing Information for complete Boxed Warning and other important safety information.

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.

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.

Investor Contact:
Courtney Dugan
VP, Head of Investor Relations
cdu@ymabs.com

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