Y-mAbs Announces Presentation of Naxitamab Data at ASCO

May 26, 2023

NEW YORK, May 26, 2023 (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, antibody-based therapeutic products for the treatment of cancer, today announced that a poster presentation featuring interim clinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody, in combination with granulocyte-macrophage colony-stimulating factor (“GM-CSF”) will be presented at the American Society of Clinical Oncology (“ASCO”) Annual Meeting to be held June 2-6, 2023, in Chicago, Illinois.

Patients with high-risk neuroblastoma (“HR-NB”) commonly develop metastases in the bone and/or bone marrow. Approximately 15% of HR-NB patients are refractory to induction therapy and approximately 50% will relapse. The ongoing Phase 2 Trial 201 (NCT03363373) evaluates naxitamab in combination with granulocyte-macrophage colony-stimulating factor (“GM-CSF”) in patients with relapsed or refractory HR-NB with residual disease limited to bone and/or bone marrow. Patients with disease in soft tissues or actively progressing disease were excluded from the trial.

Curie Score (“CS”) is a semi-quantitative scoring system used to assess the extent of bone metastases and treatment response. Higher CS indicates more extensive bone involvement and may suggest a poorer prognosis.

An interim analysis of Trial 201 (data cutoff December 31, 2021) included 52 patients in the efficacy group and 74 patients in the safety group. The efficacy analyses included the overall response rate (ORR; complete response or partial response) and the reduction in CS by baseline disease status, i.e., refractory or relapsed disease. Clinically meaningful ORRs and reductions in CS were seen in patients regardless of baseline disease status. The ORR was 58% in patients with refractory disease and 42% in patients with relapsed disease. Furthermore, from a mean baseline CS of 5.5 and 5.7 in the refractory and relapsed subgroups (range 1-20 across the two subgroups), the mean change to end of naxitamab treatment was -4.2 and -1.2, respectively. Maximum reductions in CS for relapsed and refractory subgroups were -17 and -18, respectively. Overall, the most common naxitamab related serious adverse events were hypotension, pain, urticaria, and bronchospasm. Baseline CS did not affect the safety profile of naxitamab. Patients with refractory disease had a lower frequency of serious naxitamab related adverse events compared to patients with relapsed disease.

Naxitamab was licensed by the Company from Memorial Sloan Kettering (“MSK”). MSK has institutional financial interests in the compound.

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 in the United States by the FDA under accelerated approval based on overall response rate and duration of response. Continued approval for this indication is 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 (https://labeling.ymabs.com/danyelza) 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, antibody-based therapeutic cancer products. In addition to conventional antibodies, the Company’s technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company’s broad and advanced product pipeline includes one FDA-approved product, DANYELZA (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate, omburtamab, which targets tumors that express B7-H3.

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 The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements with respect the potential of naxitamab to treat high-risk neuroblastoma, the safety profile of naxitamab, expectations with respect to Trial 201, including with respect to results and timing, the Company’s product candidates and pipeline, including with respect to the development of naxitamab, the Company’s presentation at ASCO, 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” 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 our financial condition and need for additional capital; the risks that actual results of our restructuring plan and revised business plan will not be as expected; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of our product candidates; development of our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock, risks associated with the COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto; including inflation and uncertain global credit and capital

markets; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2022, our Quarterly Report on Form 10-Q for the quarter ending March 31, 2023 and in our other SEC filings. 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.

DANYELZA®, OMBLASTYS® and Y-mAbs® are registered trademarks of Y-mAbs Therapeutics, Inc.

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