Y-mAbs Provides Regulatory Update on Omburtamab for the Treatment of Patients with Neuroblastoma

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NEW YORK, June 23, 2021 (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 it has recently concluded a Type B meeting with the U.S. Food and Drug Administration (“FDA”) regarding omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.

At the Type B meeting with the FDA, available data from external historical control groups and plans for statistical analyses to compare such data with the data from Study 03-133 were discussed. Based on our discussions with the FDA, we believe we now have a clearer path towards the resubmission of the omburtamab BLA to the FDA. Y-mAbs agreed to provide the agency with additional detailed data and the statistical analysis plan (“SAP”) and anticipates being able to do so during the third quarter of 2021. Upon receiving the FDA’s feedback on these items, we expect to move forward and request a Type B pre-BLA meeting. Pending a positive Type B pre-BLA meeting, we aim to initiate rolling resubmission of the omburtamab BLA by the end of the year.

“Although we are moving the timeline into the fourth quarter, we believe we now have a clearer path towards the resubmission of the BLA for omburtamab, which, if approved, would address an important unmet medical need,” stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, “We are very pleased to be aligned with the FDA on the next step towards the resubmission of the omburtamab BLA, and believe that, if approved, omburtamab can be of significant benefit to children with CNS/leptomeningeal metastasis from neuroblastoma.”

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed omburtamab, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the compound.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The Company has a broad and advanced product pipeline, including one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage 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 about our business model and development, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; regulatory, marketing and reimbursement approvals; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements; developments relating to our competitors and our industry; 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; 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 pandemic caused by the coronavirus known as COVID-19 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, 2020 filed with the SEC 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.

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