Y-mAbs Provides Regulatory Update on Omburtamab

April 20, 2021

NEW YORK, April 20, 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 a regulatory update for omburtamab, which is an investigational, monoclonal antibody that targets B7-H3 and has been radiolabeled before intraventricular central nervous system (“CNS”) administration. B7-H3 is an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types.

Y-mAbs recently concluded a Type B meeting with the U.S. Food and Drug Administration (“FDA”) regarding omburtamab and received requests from the FDA for additional data concerning the granularity of data from our identified historical control groups. In order to agree on a statistical analysis plan (“SAP”), this additional granularity data is being collected and we anticipate submitting it to the FDA by the end of April. An additional Type B meeting has been scheduled for June 1, 2021 to discuss the SAP based on review of the additional data. We continue to be in close dialog with the FDA and maintain our aim of resubmitting the Biologics License Application (“BLA”) for omburtamab late in the second quarter or in the third quarter of 2021.

"We believe omburtamab is on track to potentially become the first FDA approved targeted therapy for pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma, addressing an important unmet medical need, where no standard therapy is currently available," said Thomas Gad, founder, Chairman and President of Y-mAbs.

Dr. Claus Moller, the Company’s Chief Executive Officer, continued, “We believe omburtamab can potentially address a significant unmet medical need for children with CNS/leptomeningeal metastasis from neuroblastoma, and we continue to work closely with the FDA to resubmit the omburtamab BLA. In addition, we are targeting submission of a Marketing Authorization Application to the European Medicines Agency on April 30, 2021.”

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 interest related to the compound and Y-mAbs.

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,” “targeted,” “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 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, 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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