



Y-mAbs Announces Scheduling of FDA Advisory Committee Meeting for Omburtamab

September 01, 2022

NEW YORK, Sept. 01, 2022 (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 meeting of the Oncologic Drugs Advisory Committee ("ODAC") of the U.S. Food and Drug Administration ("FDA") has been scheduled for October 28, 2022 to review the Company's Biological License Application ("BLA") for its product candidate, OMBLASTYS® (omburtamab), an investigational radiolabeled antibody construct. Y-mAbs resubmitted the BLA for OMBLASTYS on March 31, 2022, and the FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 30, 2022, for the completion of its priority review of the OMBLASTYS BLA.

"We look forward to the October 28, 2022 meeting with the Advisory Committee, as well as to continuing our dialogue with the FDA about OMBLASTYS and the important data, which we believe supports approval," said Thomas Gad, President, and Interim Chief Executive Officer. "This is another key step towards providing a potential treatment for pediatric patients 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 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 at the registration-stage, 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 regarding expected regulatory activities, including potential approval and commercialization of OMBLASTYS® (omburtamab) in the United States and the timing thereof, 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," "goal," "aim," 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 COVID-19 pandemic, risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, 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, 2021, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, 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 except as required by law.

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

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