Y-mAbs Announces Outcome of FDA Advisory Committee Meeting on Omburtamab

October 28, 2022

NEW YORK, Oct. 28, 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 the outcome of the meeting of the U.S. Food and Drug Administration ("FDA") Oncologic Drugs Advisory Committee ("ODAC"), which reviewed investigational ^{131}I-omburtamab ("omburtamab") for the treatment of CNS/leptomeningeal metastasis from neuroblastoma. The committee voted 16 to 0 that the Company had not provided sufficient evidence to conclude that omburtamab improves overall survival.

"We are disappointed by the outcome of today's meeting, as patients with CNS/leptomeningeal metastasis from neuroblastoma are in need of effective and safe treatment options," said Thomas Gad, President, and Interim Chief Executive Officer. "Y-mAbs is committed to working closely with the FDA on their review of the Biologic License Application ("BLA") for omburtamab ahead of their decision. We want to thank all of the patients, caregivers, and healthcare providers who participated in the studies of this life-threatening condition."

ODAC reviewed data from omburtamab's clinical development program with a focus on study 03-133 (a pivotal phase 1 study) and study 101 (a pivotal phase 2 study) as well as the historical control group.

Y-mAbs BLA submission for omburtamab was accepted for Priority Review by the FDA on May 31, 2022, with a Prescription Drug User Fee Act ("PDUFA") target date of November 30, 2022. The FDA is not bound by the Advisory Committee's recommendations but generally takes the recommendation into consideration when making its decision.

Researchers at 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, OMBLASTYS® (^{131}I-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 potential approval of omburtamab in the United States and the timing thereof; 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.

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