Y-mAbs Announces Complete Response Letter for Omburtamab Biologics License Application

December 01, 2022

NEW YORK, Dec. 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 the U.S. Food and Drug Administration ("FDA") has issued a complete response letter ("CRL") for the Biologics License Application ("BLA") for the investigational medicine ^{131}I-omburtamab ("omburtamab") for the treatment of CNS/leptomeningeal metastasis from neuroblastoma.

The letter indicates that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This is consistent with the outcome of the Oncologic Drugs Advisory Committee Meeting in October. The CRL includes a recommendation for meeting with the agency to discuss adequate and well-controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile.

Y-mAbs is assessing the implications of the CRL and its plans for the omburtamab program.

"We are disappointed by the CRL but not surprised based on the outcome of the ODAC meeting on October 28. We want to express our gratitude to all the patients, their families, and investigators who have participated in our clinical trials and advocated for the advancement of omburtamab," said Thomas Gad, President, and Interim Chief Executive Officer. "While we evaluate the implications of the CRL for the future of omburtamab, we are excited about refining our focus primarily to drive growth from DANYELZA and validate our SADA platform in the clinic, with the goal of bringing innovative solutions to patients and value to our shareholders.

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 our expectations with respect to the omburtamab program; our expectations with respect to increasing efforts and refining focus on DANYELZA®, our SADA platform, and the rest of our pipeline; our goal of bringing innovative solutions to patients and value to our shareholders; 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, June 30, 2022, and September 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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