The CHMP has Adopted a Negative Opinion for Omburtamab for the Treatment of CNS/LM Metastasis from Neuroblastoma in Europe

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NEW YORK, Dec. 16, 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 European Committee for Medicinal Products for Human use (“CHMP”) has adopted a negative opinion recommending a refusal of the marketing authorization for omburtamab for the treatment of CNS/leptomeningeal metastasis from neuroblastoma in Europe.

"This recommendation by the CHMP is disappointing given the significant unmet medical need, which exists for patients with CNS/LM neuroblastoma who have no approved therapies available. CHMP considered that it was not possible to conclude on the effectiveness of omburtamab as the main study did not have a randomized comparator. The company does not believe it is feasible to conduct a randomized study in a life-threatening disease where no other approved therapy is available to these children," said Thomas Gad, founder, President and Interim Chief Executive Officer. "Our focus is now on assessing the implications of the negative opinion and our plans for the omburtamab program.”

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed omburtamab, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests 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 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® (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 omburtanab program and the clinical profile of omburtamab; the development and commercialization of our products, product candidates and product pipeline; ; 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 filed with the the Securities and Exchange Commission (the “SEC”) and in our other SEC filings, including our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022, June 30, 2022, and September 30, 2022 as well as 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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