Y-mAbs Provides Regulatory Update on Omburtamab for the Treatment of Patients with Neuroblastoma

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NEW YORK, Oct. 05, 2020 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the “Company” or “Y-mAbs”) (Nasdaq: YMAB), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today announced that Y-mAbs has received a Refusal to File letter from the U.S. Food and Drug Administration (“FDA”) regarding the Biologics License Application (“BLA”) for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma, which was submitted in August 2020.

Upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control (“CMC”) module and the Clinical module of the BLA require further detail. No additional non-clinical data have been requested or are required.

Y-mAbs is confident that it can address all points raised by the FDA, including providing the requested additional CMC information and supplementary data from Study 101, which will include tumor response data from patients with evaluable disease among the first 24 patients included in the protocol.

The Company will request a Type A meeting with the FDA as soon as possible, and plans to work in close dialog with the Agency in order to amend the BLA with the goal of resubmitting the BLA before the end of 2020.

Investor Call and Webcast

Y-mAbs will hold an investor conference call to discuss this update on October 6, 2020 at 9:00 a.m. EDT.

Investors are invited to listen to a live webcast of the call by dialing 877-407-0792 in the U.S. or 201-689-8263 for international callers, Conference ID: 13711563. To access a live webcast of the update, please use the following link: http://public.viavid.com/index.php?id=141792.

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 and in Y-mAbs.

About Y-mAbs

Y-mAbs is a late-stage clinical 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 two pivotal-stage product candidates - naxitamab and omburtamab - which target tumors that express GD2 and B7-H3, respectively.

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 and commercialization plans; current and future clinical and pre-clinical studies and our research and development programs; 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,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “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 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 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 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.

“Y-mAbs” is a registered trademark of Y-mAbs Therapeutics, Inc.

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