Y-mAbs Announces Completion of Pre-BLA Meeting with FDA for Omburtamab

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NEW YORK, Feb. 11, 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 it recently completed a Pre-Biologics License Application (“pre-BLA”) meeting with the U.S. Food and Drug Administration (“FDA”) regarding a potential pathway for FDA approval of omburtamab for the treatment of patients with CNS/leptomeningeal metastases from neuroblastoma. The Company expects to resubmit the BLA for omburtamab by the end of the first quarter 2022.

A data readout from a single-center clinical study (Study 03-133) of omburtamab conducted at Memorial Sloan Kettering (“MSK”), where 107 evaluable patients with CNS/leptomeningeal metastases from neuroblastoma received up to two doses of radiolabeled omburtamab, showed that patients had a median survival of 50.0 months, with the final median not yet being reached. The Company intends to submit the complete clinical data package in the BLA and announce the data later this year.

“We are pleased with the outcome of the pre-BLA meeting for omburtamab providing a clear regulatory path forward for the resubmission of the BLA. We believe omburtamab has the potential to make a meaningful impact in addressing a substantial unmet medical need for children suffering from high-risk neuroblastoma brain tumors and may potentially add an important treatment option to doctors and families facing this diagnosis,” said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, “We believe that we can resubmit the omburtamab BLA by the end of the first quarter 2022. We have been working closely with the agency to get to this point, and we will be applying for full approval. I am very grateful to the FDA and my team for the high-level constructive collaboration that has been exercised to get to this pivotal point.”

Researchers at MSK developed omburtamab, which is exclusively licensed by MSK to Y-mAbs. As a result of the licensing arrangement, MSK has institutional financial interest related to the compound.

About Y-mAbs

Y-mAbs is a commercial-stage 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 one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, 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 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’’ 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 pandemic caused by the coronavirus known as COVID-19 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, 2020 filed with the SEC 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.

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