Y-mAbs Announces Successful Pre-BLA Meeting with FDA for Naxitamab

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NEW YORK, July 08, 2019 (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 it has completed a successful Type B Pre-Biologics License Application (“Pre-BLA”) meeting with the U.S. Food and Drug Administration (“FDA”) regarding a potential pathway for FDA approval of naxitamab for the treatment of patients with relapsed/refractory high-risk neuroblastoma.

At the meeting, the Company reached alignment with the FDA on an Accelerated Approval Pathway for naxitamab along with a rolling BLA submission. The Company expects to submit the Clinical/Safety portion and the non-Clinical portion of the BLA in November 2019. For the CMC portion, the Company believes it will have sufficient data from the process performance qualification (“PPQ”) batches to complete the CMC portion in early 2020. However, Y-mAbs is still investigating possibilities for accelerating the submission of the CMC portion, and hope to comply with the FDA requirements at an earlier time.

Under naxitamab’s breakthrough therapy designation (“BTD”), the compound qualifies for a Rolling BLA, which enables individual modules of the application to be submitted by the Company and reviewed by the FDA on a rolling basis, rather than waiting for all sections to be completed before submission. The rolling application process will provide the Company with the opportunity for ongoing communications with the FDA, and, during this rolling process, the Company anticipates that it will be able to address any substantial matters raised by the FDA.

Based on the previously announced efficacy data from Study 12-230 in relapsed/refractory high-risk neuroblastoma patients at Memorial Sloan Kettering Cancer Center (“MSK”), the FDA determined that efficacy data from all 37 patients of the Company’s multicenter Study 201 would not be required for the BLA filing. The FDA advised the Company that the available data for the first group of patients treated outside MSK in Study 201 would be sufficient for the BLA filing. The first group consists of 24 patients, of which 11 were evaluable prior to the pre-BLA meeting and showed an overall response rate (“ORR”) of 73%, including 55% complete responses (“CR”), as assessed by the investigators. The Company intends to announce the complete dataset for Study 201 once the data becomes available.

“The positive outcome of the Pre-BLA meeting will be consequential for high-risk neuroblastoma patients waiting to get access to this new outpatient treatment with encouraging data,” stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, “We are pleased to see that the clinical data previously generated at MSK was able to be replicated at other sites. We believe that an ORR of 73% may place naxitamab in a strong position in the market for the treatment of high-risk neuroblastoma.”

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 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 Therapeutics, Inc.
230 Park Avenue, Suite 3350
New York, NY 10169
USA

+1 646 885 8505

E-mail: info@ymabs.com

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