Y-mAbs Announces Recruitment Status for Pivotal Trials

July 1, 2019

NEW YORK, July 01, 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 the status of patient recruitment for the Company’s two pivotal phase II trials, one for omburtamab for the treatment of CNS/LM from neuroblastoma and the other for naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma.

As of the end of June 2019, all of the 18 planned omburtamab patients have been enrolled. The Company expects the study to remain open and continue enrolling patients until the product potentially becomes available on the market and believes it remains on target to file a biologic license application (“BLA”) by the end of 2019 under the breakthrough therapy designation (“BTD”) the Company previously received from the FDA. The Company has also previously received orphan drug designation (“ODD”) and a rare pediatric disease designation (“RPDD”) for omburtamab from the FDA, in each case for the treatment of CNS/LM from neuroblastoma. The RPDD qualifies the Company for receipt of a priority review voucher (“PRV”) upon approval of omburtamab for the treatment of CNS/LM from neuroblastoma, if such approval occurs.

For naxitamab, more than 30 patients of a planned total of 37 patients in the Company’s Study 201 have been enrolled as of the end of June 2019. The Company expects the remaining patients to be included in the coming weeks and believes it remains on target for a BLA filing in 2019 under the BTD the Company previously received from the FDA for naxitamab in combination with GM-CSF for the treatment of relapsed/refractory high-risk neuroblastoma. The Company has also previously received ODD and a RPDD from the FDA for naxitamab, in each case for the treatment of relapsed/refractory high-risk neuroblastoma. The RPDD qualifies the Company for receipt of a PRV upon approval of naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma, if such approval occurs.

“We are approaching an important milestone by reaching our initial patient recruitment goals for both compounds and focus on advancing these treatments to give children access,” stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, “We believe the two important BLA filings are on track in line with our timelines and previous guidance. We salute and thank health authorities, clinical sites and our staff for their combined efforts in moving these compounds forward towards registration. We hope to see both of these new and important cancer treatments on the market in 2020. We believe these new product candidates have the potential to become historic milestones for pediatric oncology.”

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

Source: Y-mAbs Therapeutics, Inc