Y-mAbs Announces Completion of Submission of Omburtamab Biologics License Application to FDA

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NEW YORK, Aug. 06, 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 on August 5, 2020, the Company completed the submission of its Biologics License Application ("BLA") under the FDA's Rolling Review process for omburtamab. Omburtamab is an investigational, monoclonal antibody that targets B7-H3, an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types. The omburtamab BLA is for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. The submission is based on the safety and efficacy results of the pivotal Phase 2 studies 101 and 03-133, which the Company expects to present at a venue later this year.

"I am excited to see the completion of Y-mAbs' second BLA submission this year in neuroblastoma. As children treated for high-risk systemic neuroblastoma potentially experience longer systemic remissions, we expect more patients eventually relapsing with brain metastasis and there is currently no standard therapy available for these patients. We believe this is a key milestone for families facing CNS/leptomeningeal metastasis from neuroblastoma and for Y-mAbs. As the father of a long-term high-risk neuroblastoma survivor with CNS/Leptomeningeal metastasis, I know how important this potentially is for families faced with brain metastasis from high-risk neuroblastoma," stated Thomas Gad, Founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, "We believe omburtamab can potentially address a significant unmet medical need for children with CNS/leptomeningeal metastasis from neuroblastoma, and we look forward to working with the FDA to bring omburtamab to appropriate patients. Omburtamab is also being tested in a Phase 2 study for desmoplastic small round cell tumor and we are currently planning a Phase 2 study for diffuse intrinsic pontine glioma, as we believe omburtamab could potentially be developed for wider compartmental use."

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 related to the compound and 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; 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," "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 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.

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