



Y-mAbs Initiates Rolling Submission of Biologics License Application to U.S. FDA for Naxitamab for Treatment of Neuroblastoma

November 29, 2019

NEW YORK, Nov. 29, 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 submitted to the U.S. Food and Drug Administration ("FDA") the first portions of its Biologics License Application ("BLA") for naxitamab for the treatment of patients with relapsed/refractory high-risk neuroblastoma under the FDA's Rolling Review process.

In August 2018, naxitamab, which is an anti-GD2 monoclonal antibody, received Breakthrough Therapy Designation by the FDA, which facilitates frequent interactions with the FDA review team. The Rolling Review process allows Y-mAbs to submit individual portions of the BLA for review, rather than waiting until all portions are completed and submitted to the FDA for review. Upon potential approval, the Company intends to commercialize naxitamab in the U.S.

"We are excited to announce the initiation of the rolling BLA for naxitamab, a major milestone for Y-mAbs. Dr. Nai-Kong Cheung and his research team at Memorial Sloan Kettering Cancer Center ("MSK") started looking at immunotherapy more than three decades ago when he first studied the anti-GD2 target. Today, high-risk neuroblastoma patients are being treated with naxitamab worldwide in clinical trials addressing clear unmet medical needs of children waiting for new treatment options," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer further notes, "I am both proud and appreciative of the Y-mAbs team and our clinical investigators, who have helped to make this key milestone possible. We believe that this submission represents an important landmark for Y-mAbs and for neuroblastoma patients."

MSK has institutional financial interests with Y-mAbs in the form of equity and intellectual property interests through licensing agreements. Dr. Cheung is a founder of, holds equity interests in, and has intellectual property rights related to 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: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, 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.

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Source: Y-mAbs Therapeutics, Inc