



Y-mAbs Announces U.S. FDA Acceptance of Biologics License Application for Danyelza™ (naxitamab) for the Treatment of Neuroblastoma for Priority Review

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NEW YORK, June 02, 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 the Biologics License Application ("BLA") for Danyelza™ (naxitamab) for the treatment of patients with relapsed/refractory high-risk neuroblastoma has been accepted for priority review by the U.S. Food and Drug Administration ("FDA"). The FDA set an action date of November 30, 2020, under the Prescription Drug User Fee Act ("PDUFA"). The Agency also indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application.

"We believe that the FDA's acceptance of our BLA for priority review of our first leading antibody compound, Danyelza (naxitamab), is a significant achievement for Y-mAbs and a crucial step forward as we anticipate that Danyelza, if approved, can address a significant unmet medical need for children with relapsed/refractory high-risk neuroblastoma," stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, "We look forward to working with the Agency to bring Danyelza to appropriate patients. We are excited to move forward and plan for a seamless commercial launch of Danyelza (naxitamab), if approved."

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed naxitamab, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the product.

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 - Danyelza (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 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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