



Y-mAbs Announces FDA Acceptance of Biologics License Application for OMBLASTYS® (omburtamab) for the Treatment of Neuroblastoma for Priority Review

May 31, 2022

NEW YORK, May 31, 2022 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a commercial-stage 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 OMBLASTYS® (omburtamab) for the treatment of pediatric patients with CNS/leptomeningeal metastasis from 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, 2022, under the Prescription Drug User Fee Act ("PDUFA"). The Agency also indicated in the BLA filing communication letter that it is planning to hold an advisory committee meeting in October 2022 to discuss the application.

"We believe that the FDA's acceptance of our OMBLASTYS® BLA for priority review is a significant achievement for Y-mAbs and a crucial step forward as we anticipate that OMBLASTYS, if approved by the FDA, can address a significant unmet medical need for children with CNS/leptomeningeal metastasis from high-risk neuroblastoma, where no standard therapy currently exists, potentially adding a second rare disease product to our commercial portfolio and without any significant further investment in our existing commercial infrastructure. Further, OMBLASTYS® has a Rare Pediatric Disease Designation which, if approved, will provide Y-mAbs with a Priority Review Voucher, our second PRV, which would further strengthen our financial position as we would seek to monetize the OMBLASTYS® PRV," stated Thomas Gad, Founder, President and Interim CEO. "We look forward to working with the Agency to bring OMBLASTYS® to the appropriate patients. We are excited to move forward and plan for a seamless commercial launch of OMBLASTYS®, if approved by the FDA."

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 in the compound and in Y-mAbs.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products. In addition to conventional antibodies, the Company's technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company's broad and advanced product pipeline includes one FDA-approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate at the registration-stage, OMBLASTYS® (omburtamab), which targets tumors that express B7-H3.

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, commercialization and product distribution 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," "hope," "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, risks associated with the pandemic caused by the coronavirus known as COVID-19 and its variants such as Delta and Omicron, risks associated with Russia's recent invasion of Ukraine 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 for the year ended December 31, 2021 filed with the SEC 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.

DANYELZA®, OMBLASTYS® and Y-mAbs® are registered trademarks of Y-mAbs Therapeutics, Inc.

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