Y-mAbs Announces Pivotal Data for Omburtamab

October 03, 2022

NEW YORK, Oct. 03, 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 clinical data on the Company’s product candidate OMBLASTYS® (^{131}I-omburtamab) for the treatment of CNS/leptomeningeal metastasis from neuroblastoma. Data was presented by Dr. Kim Kramer from Memorial Sloan Kettering Cancer Center (“MSK”) at the International Society of Pediatric Oncology (“SIOP”) Annual Congress held September 28 through October 1, 2022, in Barcelona, Spain.

In an oral presentation, Dr. Kramer presented interim results for 32 patients enrolled in the Company’s ongoing pivotal 101 multicenter study of omburtamab radiolabeled with Iodine-131. The results showed a twelve-month overall survival (“OS”) of 73.5%, with a median follow-up of 25 months. Further, the interim results showed an objective response rate (“ORR”) of 31.3% in the patients with measurable disease after central review based on Response Assessment in Neuro-Oncology (“RANO”) criteria and European Association of Neuro-Oncology (“EANO")/ European Society for Medical Oncology (“ESMO”) criteria, and that a total of 75.0% of the patient with measurable disease achieved disease control. Serious Adverse Events (“SAE”) was found in 40.6% of the patients and were mostly related to myelosuppression.

“We are excited to report these data that together with Study 03-133 is the basis of our BLA,” said Thomas Gad, President, and Interim Chief Executive Officer. “The disease burden these patient and their families are facing represent a significant unmet medical need, which we hope to be able to address with OMBLASTYS after our PDUFA date on November 30, 2022.”

Researchers at 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.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic cancer 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® (^{131}I-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 regarding expected regulatory activities, including potential approval and commercialization of OMBLASTYS® (^{131}I-omburtamab) in the United States and the timing thereof, 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”, “goal,” “aim,” 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 COVID-19 pandemic, risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, including inflation and uncertain global credit and capital markets; 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, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, 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 except as required by law.

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