Y-mAbs Announces Update on Naxitamab and Omburtamab in Neuroblastoma

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NEW YORK, Oct. 16, 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 clinical updates on naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma and omburtamab for CNS/leptomeningeal metastasis from neuroblastoma. Data was presented at the International Society of Pediatric Oncology (“SIOP”) Virtual Annual Congress held October 14 through October 17, 2020 in Ottawa, Canada. The naxitamab data was presented by Dr. Jaume Mora from SJD Barcelona Children's Hospital, and the omburtamab data was presented by Dr. Kim Kramer from Memorial Sloan Kettering Cancer Center (“MSK”).

Naxitamab
In a poster presentation, Dr. Mora presented data from the Company’s pivotal 201 multicenter study. The central independent evaluation showed an overall rate of response (“ORR”) of 68% and the rate of complete response (“CR”) was 59% for the 22 patients. In addition, bone marrow clearance was observed with complete response in 7 of 9 patients, who had positive bone marrow at trial start. The median duration of response with long-term follow-up was 27 weeks.

“We are excited to share this new clinical data for naxitamab, which we believe could be a very important new treatment for high-risk neuroblastoma patients, if approved. Naxitamab is administered in an outpatient setting, and the FDA previously set a PDUFA date of November 30, 2020,” said Thomas Gad, founder, Chairman and President.

Omburtamab
In an oral presentation, Dr. Kramer presented planned interim results for 17 patients enrolled on the Company’s pivotal 101 multicenter study. The study showed a twelve-months overall survival (“OS”) of 87%, with a median follow-up of 26 weeks. This compares to an OS of approximately 30% in a historic control group previously disclosed by the Company.

“The preliminary OS results from the multicenter Study 101 are encouraging and appears almost identical to the results of Study 03-133, which was conducted at MSK. While recruitment is still ongoing, we are very pleased to see the preliminary omburtamab data in the multicenter setting appearing supportive of the conclusions from the MSK data. We believe the preliminary survival curves are very similar to the original MSK data, and this is good news for children with CNS/leptomeningeal metastasis from neuroblastoma,” said Claus Moller, Chief Executive Officer.

Researchers at MSK developed naxitamab and omburtamab, which are exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests related to the compounds and Y-mAbs.

About Y-mAbs

Y-mAbs is a development-stage 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.

“Y-mAbs” is a registered trademark of Y-mAbs Therapeutics, Inc.

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