Y-mAbs Announces Update on Omburtamab in DSRCT

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NEW YORK, Nov. 15, 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 a clinical update on omburtamab for Desmoplastic Small Round Cell Tumor ("DSRCT"). Data was presented at the 2019 Connective Tissue Oncology Society ("CTOS") Annual Meeting in Tokyo, Japan on November 15, 2019, by Dr. Shakeel Modak from Memorial Sloan Kettering Cancer Center ("MSK") in New York.

DSRCT is an aggressive malignancy that typically presents as intraabdominal sarcomatosis in young males. Less than 100 patients are diagnosed each year in the US, and given this incidence, optimal treatment has not yet been defined. Patients with DSRCT have a very poor prognosis with limited five year survival. Even for those patients where Gross Total Resection ("GTR") is possible, five year Overall Survival ("OS") appears to be approximately 20%. Based on observations from MSK, Whole Abdominalpelvic Intensity-Modulated RadioTherapy ("WA-IMRT") may be advisable for all patients whose tumor can be resected.

Data reported by Dr. Modak was based on evaluation of 33 GTR patients treated at MSK from 2009 to 2017. A total of 24 patients from a Phase I study at MSK received WA-IMRT in combination with omburtamab Interperitoneal Radio Immunotherapy ("IP-RIT") and nine patients received WA-IMRT without omburtamab IP-RIT. The study showed a median OS of 41 months for the DSRCT patients who did not receive omburtamab IP-RIT and 59 months for those receiving omburtamab IP-RIT. The data presented at CTOS indicates that adding IP-RIT with iodinated omburtamab to the standard WA-IMRT treatment appears to be well tolerated. Furthermore, adding omburtamab IP-RIT to GTR improved the five year Kapplan Meier estimated OS from a historical rate of approximately 20% to approximately 40%. While this approach may not help patients who do not achieve GTR of DSRCT, we believe that it may help patients with microscopic disease and help prevent relapse. Lack of evaluable disease means that survival is the only relevant endpoint for these patients.

"We are excited to announce this update for omburtamab in DSRCT, and have recently started a Phase II trial at MSK. DSRCT represent a clear unmet medical need. We plan to advance omburtamab for the benefit of these patients. It is very encouraging to continue to witness omburtamab produce significant data in additional difficult indications, providing further evidence of omburtamab's potential across B7-H3 positive solid tumors," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer further notes, "We are very pleased to see these survival data. This is good news for the DSRCT patients who typically are male teenagers and young adults. We believe that the data illustrates the width of compartmental use of radiolabeled omburtamab, which potentially could be applied to other peritoneal malignancies."

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.

About Memorial Sloan Kettering

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

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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