Y-mAbs Announces Positive Omburtamab Clinical Data

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NEW YORK, Oct. 28, 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 the treatment of central nervous system (CNS) leptomeningeal metastases from neuroblastoma and a number of additional cancer indications. Data was presented at the International Society of Pediatric Oncology (SIOP) Annual Congress in Lyon, France on October 26, 2019 by Dr. Kim Kramer from Memorial Sloan Kettering Cancer Center (MSK) in New York.

An updated data readout as of June 30, 2019 from a single-center study at MSK (Study 03-133), where patients with CNS/leptomeningeal metastases from neuroblastoma received up to two doses of radiolabeled omburtamab, showed that for the 107 evaluable patients, the median survival had increased to 50.8 months, with the final median not yet being reached. This compared well to a median survival of 47.1 months at the prior data readout based on the first 93 patients in the study.

In addition, 68 patients diagnosed with other CNS cancers, including metastatic tumors had received a total of 201 injections of omburtamab. Injections were routinely administered in an outpatient setting. Rare self-limited adverse events included grade 1 or 2 fever, headache, vomiting; 3 injections were associated with grade 3 toxicities requiring discontinuation of therapy including chemical meningitis and increasing communicating hydrocephalus. Although not a dose limiting toxicity, myelosuppression occurred in patients who had received craniospinal radiation and at dose levels exceeding 60mCi. The primary CNS diagnoses included medulloblastoma (n=27), ependymoma (n=9), and embryonal tumors with multilayered rosettes (n=4), while metastatic tumors included sarcoma (n=9), melanoma (n=5), and other tumors (n=14). As of today, 26 of the 68 patients with these highly lethal diagnoses remain alive.

“We are excited to announce this updated data for omburtamab in CNS/leptomeningeal metastases from high-risk neuroblastoma further confirming the importance of omburtamab in addressing this unmet medical need. Further very interesting proof of concept data for other CNS cancers suggests potential clinical utility for use of omburtamab beyond neuroblastoma. Overall survival data have already been accepted by the FDA as supportive for our Breakthrough Therapy Designation, and we still plan to initiate the rolling BLA submission for omburtamab in December this year,” 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 the variety of other CNS cancers and metastatic cancers treated in this trial at MSK. The experience gained from these 68 patients pave the way for future potential label expansion of compartmental use of the radiolabeled omburtamab as well as our new clinical program for omburtamab-DTPA, for which we expect to file an IND within the next few months.”

Researchers at MSK developed the therapeutic products referenced in this statement, which are 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.

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.

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 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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