# Y-mAbs Announces Naxitamab Update

October 25, 2019

NEW YORK, Oct. 25, 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 that a clinical update on one of the Company's lead products, naxitamab for the treatment of neuroblastoma and osteosarcoma, was made at the International Society of Pediatric Oncology (SIOP) Annual Congress held in Lyon, France. Naxitamab is currently being evaluated for the treatment of pediatric patients with relapsed or refractory high-risk neuroblastoma, osteosarcoma and other GD2-positive tumors. An oral presentation was made by Dr. Shakeel Modak, and a total of five (5) poster presentations were made by Dr. Brian H. Kushner and Dr. Filemon Dela Cruz, all from Memorial Sloan Kettering (MSK) in New York.

Data from 28 patients with primary refractory high-risk neuroblastoma in Study 12-230 (NCT01757626) was presented. This comprises patients refractory to intensive induction therapy, and more than half of such patients also refractory to second line chemotherapy. Essentially, this data relates to a subset of patients from Study 12-230 that demonstrate better than expected outcomes, including a 78% overall response rate. The patients received at least five (5) cycles of therapy post major response and a subset subsequently went on to receive the Company's investigational GD2-GD3 Vaccine at MSK. Overall, in this population a 50% two-year progression free survival was observed.

Another subset consisted of 35 patients with relapsed neuroblastoma resistant to salvage therapy, of which 30 patients were evaluable for response in the 12-230 Study. One third of the patients had two (2) or more relapses prior to enrollment and 89% of patients had previously received anti-GD2 therapy. Patients in this subset had a 36% rate of two-year progression-free survival and an overall response rate (ORR) of 37%, which indicated clinical benefit in this difficult to treat population.

Data was also presented for patients with high-risk neuroblastoma in second or later complete remission. 44 patients with no evidence of disease (NED) were treated with naxitamab and GM-CSF at MSK as maintenance therapy. In this population, where 88% had previously received an anti-GD2 therapy and 30% had previously received two or more lines of anti-GD2 therapy, a two-year progression-free survival of 52% was observed. Some of these patients went on to receive the Company's investigational GD2-GD3 Vaccine at MSK. Due to the absence of macroscopic evaluable disease, these patients were not evaluable for a formal tumor response grading. Therefore, these patients will not form a part of the Company's efficacy data set for its rolling biologics license application (BLA) filing currently planned to be initiated in November 2019.

Finally, safety data from the Phase II osteosarcoma trial, Study 15-096, for the 25 patients enrolled in the study at MSK was presented. Patients who had recurrent disease and two (2) or more complete remissions were treated with naxitamab and GM-CSF, administered to the patients in an outpatient setting. The Company plans to initiate a multi-center trial in 2020.

"It is both exciting and encouraging to see the efficacy data that naxitamab produces in neuroblastoma and the safety data in osteosarcoma presented this week at SIOP. We believe that we are on track to initiate the rolling BLA filling for naxitamab in combination with GM-CSF for the treatment of relapsed/refractory high-risk neuroblastoma in November this year under the breakthrough therapy designation (BTD), which the Company previously received from the FDA," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, further noted, "We are very pleased to see the response rates previously reported from Study 12-230 holding up. We are genuinely impressed with the duration of responses, and we have also observed this being replicated for the 24 patients in our international multicenter Study 201, which, we believe, will be pivotal for our rolling BLA filing for naxitamab. Based on our pre-BLA meeting with the FDA in June 2019, where data from the first 11 patients from Study 201 had been analyzed and showed a more than 70% overall response rate, we believe the response rate seems to be holding up for the complete group of patients in Study 201. We believe that this is good news for neuroblastoma patients."

**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 (2) 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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