Y-mAbs Announces Positive Naxitamab Frontline Data

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NEW YORK, Dec. 11, 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 positive frontline data for naxitamab will be presented at the Company's R&D event, which takes place in New York City today at 12 p.m. Eastern. Key opinion leaders, including Dr. Shakeel Modak, M.D., MRCP and Dr. Kim Kramer, M.D., both from Memorial Sloan Kettering Cancer Center ("MSK") and Dr. Jaume Mora, M.D., Ph.D. from SJD Barcelona Children's Hospital, will discuss the current treatment landscape and unmet medical needs for high-risk neuroblastoma and other solid tumors. Members of the media and public may access the event via a live webcast.

Dr. Mora, who has experience treating frontline neuroblastoma patients with both naxitamab and a competing anti-GD2 antibody, will present clinical data from both antibodies. Data from an investigator sponsored frontline study of 34 patients with high-risk stage 4 neuroblastoma in first complete remission showed a 72% event free survival at 24 months for naxitamab patients, which compared favorably to the 63% reported at 24 months for a population of 89 patients treated with a competing anti-GD2 antibody. In addition, it was noted that only 20% of the patients treated with naxitamab received bone marrow transplant, as was the case for all patients treated with the competing anti-GD2 antibody. In terms of overall survival ("OS"), the naxitamab patients achieved an 86% OS at 24 months, compared to 84% OS for the competing anti-GD2 antibody.

The naxitamab treatment was well-tolerated, and the infusion related pain generally associated with anti-GD2 antibodies required significantly less opioids for naxitamab than for the competing anti-GD2 antibody. The use of morphica generally declined significantly after the first treatment cycle, and naxitamab required less than 15% of the morphine dose required by the competing anti-GD2 antibody. A second frontline study with naxitamab is currently ongoing at MSK in New York City, and Y-mAbs expects data from this study to be published in the first half of 2020. Y-mAbs is also planning a multicenter frontline study, which we expect to initiate in 2020.

"I am delighted and excited to welcome this excellent group of key opinion leaders to our R&D Event. It will be a great opportunity to learn more about the clinical experience of both naxitamab and omburtamab, also noting that SJD Barcelona Children's Hospital, a major pediatric center located in Barcelona, Spain, has produced very encouraging frontline naxitamab data," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer further notes, "We are excited to share the first ever frontline data from naxitamab, and believe this to be class leading clinical results. The reduced use of morphica and the convenience of giving naxitamab in an outpatient setting, shows the important role naxitamab has in addressing the clear unmet medical needs of children waiting for new treatment options."

MSK has institutional financial interests with Y-mAbs in the form of equity and intellectual property interests through licensing agreements.

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: 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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