Y-mAbs and the European Medicines Agency Pediatric Committee Reach Agreement on the Pediatric Investigation Plan for Omburtamab

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NEW YORK, Dec. 05, 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 the European Medicines Agency (“EMA”) has agreed to the Company’s proposed Pediatric Investigation Plan (“PIP”) for omburtamab. The decision was made on the basis of a positive opinion from EMA’s Pediatric Committee (“PDCO”). Omburtamab is being developed by Y-mAbs for the treatment of CNS/leptomeningeal metastases from neuroblastoma which is the indication targeted by the PIP, as well as a number of additional cancer indications.

As part of the regulatory process for the registration of new medicines in Europe, pharmaceutical companies are required to provide a PIP outlining their strategy for investigation of the new medicinal product in the pediatric population. An approved PIP is a prerequisite for filing a Marketing Authorization Application (“MAA”) for any new medicinal product in Europe.

“We are pleased to announce this important regulatory milestone. The approval of the PIP provides Y-mAbs with a clear path for registration of omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastases from neuroblastoma. We look forward to continuing to work with EMA and PDCO to bring this important therapy to the European market as soon as possible,” said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, further notes, “We are preparing the European submission of the marketing authorization application for omburtamab, and plan for submission in the second half of 2020. This is a vital step forward in our efforts of bringing omburtamab to the market in Europe, and it demonstrates the close and constructive interactions established with the regulatory authorities in Europe.”

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 product 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 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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