Y-mAbs' 177Lu-omburtamab-DTPA for the Treatment of Patients with Medulloblastoma Receives Positive Opinion on Orphan Medicinal Product Designation by EMA

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NEW YORK, June 25, 2021 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today announced that the Committee for Orphan Medicinal Products ("COMP") of the European Medicines Agency ("EMA") has recommended the granting of orphan medicinal product designation ("OMPD") in the European Union ("EU") for ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma. The positive opinion from the EMA's COMP has been sent to the European Commission ("EC"), which is expected to grant the orphan drug designation within 30 days.

Obtaining OMPD for ^{177}Lu-omburtamab-DTPA is part of an overall plan to expand the Company's European development programs and ultimately obtain orphan drug exclusivity to protect ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma in the EU.

Under the EMA's Regulation (EC) No. 141/2000 an orphan medicinal product designation gives companies access to protocol assistance and guidance on preparing a dossier that will meet European regulatory requirements and thereby maximize the chance of approval at the time of marketing authorization. Once approved, an orphan drug is also granted 10 years of market exclusivity during which directly competitive similar products cannot normally be placed on the market.

The EMA grants orphan medicinal product designation based upon several criteria, including: the life threatening and debilitating nature of the condition; the medical plausibility of the proposed orphan indication; a prevalence in Europe of less than five cases for each 10,000 of population; no satisfactory method of diagnosis, prevention or treatment exists or if such method exists the medicinal product will be of significant benefit to those affected by that condition.

Y-mAbs' founder, Chairman and President, Thomas Gad said, "We are very pleased that the COMP has issued a positive opinion for an orphan drug designation to ^{177}Lu-omburtamab-DTPA which will give us a string of development incentives."

Dr. Claus Moller, Chief Executive Officer further notes, "We believe that the orphan designation strengthens our opportunity to bring ^{177}Lu-omburtamab-DTPA to patients who desperately need alternative methods of treatment. Further, the designation marks a substantial milestone in Y-mAbs' expansion into European development."

Researchers at MSK developed omburtamab, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the product.

About Y-mAbs

Y-mAbs is a commercial-stage 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 one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, omburtamab, which targets tumors that express B7-H3.

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, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; 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," "hope," "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 in the timing of our regulatory submissions 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, risks associated with the pandemic caused by the coronavirus known as COVID-19 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 for the year ended December 31, 2020 filed with the SEC 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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