Naxitamab Receives Positive Opinion for Orphan Medicinal Product Designation Approval in the EU

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NEW YORK, Oct. 23, 2018 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq:YMAB) 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 naxitamab, one of the Company's lead product candidates, for the treatment of relapsed or refractory high-risk neuroblastoma. 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 naxitamab is part of an overall plan to expand the Company's European development program and ultimately obtain orphan drug exclusivity to protect naxitamab in the EU for the treatment of relapsed or refractory high-risk neuroblastoma.

Under the EMAs 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 success 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: the life threatening and debilitating nature of the condition; the medical plausibility of the proposed orphan indication; a prevalence in Europe of less than 5 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, President and Head of Business Development and Strategy, Thomas Gad said, "We are very pleased that the COMP has issued a positive opinion for orphan drug designation to naxitamab which will give us a string of development incentives."

Dr. Claus Møller, Chief Executive Officer, further notes, "The orphan designation strengthens our opportunity to bring naxitamab to patients who desperately need alternative methods of treatment. Further, the designation marks a substantial milestone in Y-mAbs' expansion into European development."

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 orphan drug- and other regulatory approvals, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, and other statements that are not historical facts. Words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials including if we encounter difficulties enrolling patients in our clinical trials; the risks of delays in FDA and/or EU approval of our drug candidates or failure to receive approval; the risks related to commercializing any approved new 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; our inability to enter into collaboration or alliances with partners; risks associated with protection of our intellectual property rights; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Registration Statement on Form S-1 declared effective by the SEC on September 20, 2018 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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