



Y-mAbs' Nivatrotamab for the Treatment of Patients with Neuroblastoma Granted Orphan Drug Designation and Rare Pediatric Disease Designation by FDA

October 07, 2020

NEW YORK, Oct. 07, 2020 (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 FDA has granted Orphan Drug Designation ("ODD") and Rare Pediatric Disease Designation ("RPDD") for its leading bispecific antibody program nivatrotamab for the treatment of neuroblastoma.

Nivatrotamab, a humanized bispecific anti-GD2 antibody, is currently in Phase 1 clinical development in collaboration with Memorial Sloan Kettering Cancer Center ("MSK") in patients with relapsed/refractory neuroblastoma, as well as high grade osteosarcoma and other GD2(+) solid tumors, where patients have relapsed or refractory disease that is resistant to standard therapy.

"We are very pleased with the ODD granted for nivatrotamab, as this potentially would give us seven years of market exclusivity upon market approval. The RPDD makes us eligible for a Priority Review Voucher ("PRV") upon potential approval of the biologics license application for this rare pediatric cancer. Among our leading compounds, four now have RPDDs, and this designation further increases our chances of ultimately receiving multiple PRVs," said Thomas Gad, Founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, further notes, "We are very pleased by this recognition by the FDA, and plan to expand the ongoing study with nivatrotamab into two separate Phase 2 arms in neuroblastoma and osteosarcoma, respectively, as well as a separate Phase 2 multicenter study in small cell lung cancer. We expect to submit an IND for the lung cancer study during the fourth quarter of 2020, and we are thrilled to widen nivatrotamab's clinical reach to include adult indications."

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed nivatrotamab, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the compound 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.

"Y-mAbs" is a registered trademark of Y-mAbs Therapeutics, Inc.

Contact:

Y-mAbs Therapeutics, Inc.
230 Park Avenue, Suite 3350
New York, NY 10169
USA

+1 646 885 8505

E-mail: info@ymabs.com

