Y-mAbs Announces FDA Clearance of IND for its Lutetium-177 Labeled Omburtamab Antibody

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NEW YORK, Oct. 14, 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 announced today that the U.S. Food and Drug Administration (“FDA”) has cleared the Company’s Investigational New Drug (“IND”) application for ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma, which is the most common type of primary brain cancer in children. Medulloblastomas are invasive, rapidly growing tumors that, unlike most brain tumors, spread through the cerebrospinal fluid and frequently metastasize to different locations along the surface of the brain and spinal cord.

^{177}Lu-omburtamab-DTPA embodies the Company’s naked omburtamab antibody radiolabeled with lutetium-177, using DTPA to chelate the lutetium radioisotope to the antibody. Lutetium-177 is a beta-emitter with a half-life of 6.7 days and a maximum energy of 0.5 MeV, corresponding to a maximum soft-tissue penetration of approximately 1 mm.

We anticipate that an international multicenter Phase 1/2 clinical trial will be initiated for the screening of pediatric patients with medulloblastoma during the fourth quarter of 2020.

“Based on our clinical experience with ^{131}I-omburtamab for B7-H3 positive brain metastasis, we are excited to see ^{177}Lu-omburtamab-DTPA make its way to the clinic to establish the safety profile and to determine the maximum tolerated dose. In this study, we hope to leverage our clinical experience from treating 27 medulloblastoma patients with ^{131}I-omburtamab, again using indwelling catheters for intracerebroventricular drug delivery,” said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, “Children with medulloblastoma represent a clear unmet medical need, and we are very pleased to move this product to the clinic. In addition, we have submitted a separate IND for a basket trial in B7-H3 positive CNS/LM cancers in adults to leverage our experience from treating more than 25 adults with ^{131}I-omburtamab. We expect to initiate the study for the first adult patients to be treated with ^{177}Lu-omburtamab-DTPA during the fourth quarter of 2020, and we are genuinely thrilled to widen our clinical reach to include adult indications.”

Researchers at Memorial Sloan Kettering (“MSK”) developed the omburtamab antibody, 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; 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,” “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 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.

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