Y-mAbs' GD2-GD3 Vaccine Granted Rare Pediatric Disease Designation

December 12, 2019

NEW YORK, Dec. 12, 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 and immunotherapeutic products for the treatment of cancer, today announced that its GD2-GD3 Vaccine has been granted a Rare Pediatric Disease Designation ("RPDD") by the FDA for the treatment of neuroblastoma.

The GD2-GD3 Vaccine was originally developed by researchers at Memorial Sloan Kettering ("MSK"), and licensed to MabVax Therapeutics Holdings, Inc. ("MabVax"), which sublicensed the compound for the treatment of neuroblastoma to Y-mAbs in 2018. Upon approval by the FDA of the GD2-GD3 Vaccine, Y-mAbs may be eligible for a Priority Review Voucher ("PRV") and will share 20% of the net income received from the potential sale of such PRV with MabVax.

The GD2-GD3 Vaccine is being tested in a single center clinical trial at MSK where children with neuroblastoma, who are in remission, are being treated with seven subcutaneous injections during a year (ClinicalTrials.gov Identifier: NCT00911560) to prevent relapse.

"This Rare Pediatric Disease Designation is of great importance to Y-mAbs, which is now eligible for a PRV upon approval of the biologics license application ("BLA") for this rare pediatric cancer. Among our three leading compounds, Y-mAbs now has four RPDDs, and this designation further increases our chances of ultimately receiving multiple PRVs. The GD2-GD3 Vaccine is an important addition to our Naxitamab program for children diagnosed with high-risk neuroblastoma. Y-mAbs continues to focus on maximizing its portfolio of rare pediatric disease assets addressing clear unmet medical needs in pediatric cancers while utilizing government programs in place for companies committed to rare pediatric cancers," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer further notes, "We are committed to bringing GD2-GD3 Vaccine to children with neuroblastoma, a life-threatening cancer with a clear unmet medical need. We are very pleased with the designation granted by the FDA, and plan to start a multicenter Phase II trial in neuroblastoma in 2020."

MSK researchers developed the GD2-GD3 Vaccine and have intellectual property and other interests related to the subject of the research described in this release. MSK has institutional financial interests related to this research in the form of intellectual property rights and equity interests in Y-mAbs, the company licensing and commercializing this intellectual property.

About Rare Pediatric Disease Program

In 2012, the United States Congress effectuated a Rare Pediatric Disease Priority Review Voucher Program to incentivize pharmaceutical sponsors to develop drugs for rare pediatric diseases. A sponsor who obtains approval of a new drug application ("NDA") or biologics license application ("BLA") for a rare pediatric disease may be eligible for a PRV, which may be redeemed to obtain priority review for a marketing application by the owner of such PRV. The PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately ten months. In December 2016, the House of Representatives approved the 21st Century Cures Act, which among other initiatives reauthorizes the PRV program for rare pediatric diseases until 2020. A drug that receives a Rare Pediatric Disease Designation RPDD before October 1, 2020 continues to be electable for a voucher if the drug is approved before October 1, 2022.

About Y-mAbs

Y-mAbs is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based and immunotherapeutic 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.

Contact

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

+1 646 885 8505

E-mail: info@ymabs.com

Source: Y-mAbs Therapeutics, Inc