Y-mAbs Signs License Agreement with SciClone for DANYELZA® (naxitamab-gqgk) and Omburtamab in China

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NEW YORK, Dec. 18, 2020 (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 announced today that it has entered into a license agreement with SciClone Pharmaceuticals International Ltd ("SciClone") to be the exclusive co-development and commercialization partner of the Company's antibodies, DANYELZA® (naxitamab-gqgk) for the treatment of patients with relapsed/refractory high-risk neuroblastoma and omburtamab, if approved, for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma in China. DANYELZA (naxitamab-gqgk) 40mg/10mL was approved by the U.S. Food and Drug Administration ("FDA") on November 25, 2020 and is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. The Company plans to resubmit its Biologics License Application ("BLA") to the FDA for omburtamab by the end of 2020 or in early 2021.

The license agreement includes Greater China, including Mainland China, Taiwan, Hong Kong and Macau. Under the terms of the agreement, SciClone will employ its development, sales, marketing and regulatory expertise to commercialize DANYELZA and omburtamab, if approved, in the territory. All other unpartnered geographies worldwide remain with the Company. Under the terms of the agreement, SciClone will pay Y-mAbs a $20 million upfront payment with the potential for Y-mAbs to receive up to $100 million in additional development, regulatory and sales milestone payments for both programs, as well as double-digit royalties on net sales for DANYELZA and omburtamab in the territory.

"We are very pleased to enter this license agreement with SciClone, and hope to see a DANYELZA and omburtamab, if approved, being made available to appropriate children with unmet medical needs in China. This partnership marks an important milestone in our aim to make our lead product and product candidate globally available," said Thomas Gad, founder, Chairman and President at Y-mAbs.

"DANYELZA and omburtamab were initially identified and sourced from Memorial Sloan Kettering Cancer Center in New York, and have been developed by Y-mAbs as novel therapies. We believe these antibodies show great promise," said Hong Zhao, President and Chief Executive Officer of SciClone. "We are excited to partner with Y-mAbs team to commercialize DANYELZA for the treatment of relapsed/refractory high-risk neuroblastoma and omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma, if approved. This strategic partnership recognizes SciClone's capability as a leading biotech company with integrated platform of development and commercialization."

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

About DANYELZA® (naxitamab-gqgk)

DANYELZA (naxitamab-gqgk) is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. This indication was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory trial. DANYELZA includes a Boxed Warning for serious infusion-related reactions, such as cardiac arrest and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. See full Prescribing Information for complete Boxed Warning and other important safety information.

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.

About SciClone Pharmaceuticals (Holdings) Limited

SciClone Pharmaceuticals (Holdings) Limited is a leading biopharmaceutical company with an integrated platform for product development and commercialization, focusing on some of the largest and fast-growing therapeutics areas with significant unmet medical needs in China, primarily including oncology and severe infection. Leveraging their integrated platform, SciClone has a proven track record in developing and commercializing a balanced portfolio of high-quality marketed products and innovative pipeline drugs in their focused therapeutic areas. For more information regarding to SciClone, go to: http://www.sciclone.com/

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 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 novel 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 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.

“DANYELZA” and “Y-mAbs” are registered trademarks of Y-mAbs Therapeutics, Inc.

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