Y-mAbs Announces Presentation of Naxitamab data at AACR

April 18, 2023

NEW YORK, April 18, 2023 (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, today announced that a poster presentation featuring preclinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody will be presented at the AACR Annual Meeting 2023, which takes place in Orlando, Florida from April 14-19, 2023. The poster, “Investigational novel humanized anti-GD2 antibody inhibits GD2-mediated immunosuppression by targeting GD2+ breast cancer stem-like cells,” will be presented on April 18, 2023, from 1:30 to 5:00 pm EST.

The disialoganglioside GD2 has been shown to be upregulated in triple-negative breast cancer (“TNBC”) and its high expression is associated with a poor prognosis. Furthermore, breast cancer stem-like cells (“BCSCs”) are reported to be a major contributing factor for metastatic spread of TNBC and contribute to chemotherapy resistance, making them an important target for therapeutic intervention. Currently, there are no available therapeutic tools for targeting BCSCs. New preclinical data from M.D. Anderson Cancer Center demonstrate that TNBC with high GD2 expression inhibits immune cell infiltration and that naxitamab targets GD2+ BCSCs and may be able to inhibit the growth of BCSCs by enhancing macrophage-mediated phagocytosis, NK cell-mediated ADCC, and T cell-mediated cytotoxicity.

Y-mAbs provided naxitamab (DANYELZA) to this pre-clinical investigator sponsored study (“ISS”) at M.D. Anderson Cancer Center as part of its strategy to continue to support ISS studies.

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the compound and 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 in the United States by the FDA under accelerated approval based on overall response rate and duration of response. Continued approval for this indication is 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 (https://labeling.ymabs.com/danyelza) 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 cancer products. In addition to conventional antibodies, the Company’s technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company’s broad and advanced product pipeline includes one FDA-approved product, DANYELZA (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate at the registration-stage, omburtamab, which targets tumors that express B7-H3.

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 with respect the potential of naxitamab to target GD2 and BCSCs and inhibit the growth of BCSCs by enhancing macrophage-mediated phagocytosis, NK cell-mediated ADCC, and T cell-mediated cytotoxicity, the Company’s product candidates and pipeline, including with respect to the development of naxitamab 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; the risks that actual results of our restructuring plan and revised business plan will not be as expected; 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 COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto; including inflation and uncertain global credit and capital markets; 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 for the year ended December 31, 2022 filed with the SEC 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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