Y-mAbs Announces Publication in Cancers

October 16, 2023

Naxitamab-based chemo-immunotherapy significantly improves long-term outcomes when administered early during the course of treatment

NEW YORK, Oct. 16, 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 the publication of naxitamab-based chemoimmunotherapy in patients with chemoresistant high-risk neuroblastoma ("HR-NB") in the journal *Cancers*.

"The publication in *Cancers* further validates the utilization of naxitamab early during the course of treatment for patients with high-risk neuroblastoma," said Thomas Gad, Founder, President and Interim Chief Executive Officer. "In this study, early administration of naxitamab-based chemo-immunotherapy was shown to significantly improve long-term outcomes, addressing an important unmet need in the current treatment paradigm for this critical patient group."

Approximately 50% of HR-NB patients are unable to achieve a complete response ("CR") or very good partial response ("VGPR") at the end of induction ("EOI") and have poor long term outcomes. This analysis investigated the combination of humanized anti-GD2 mAb naxitamab ("Hu3F8"), irinotecan ("I"), temozolomide ("T"), and sargramostim ("GM-CSF")—HITS—in patients with HR-NB who did not achieve a CR/VGPR to induction. Cycles were administered 3-5 weeks apart and the primary endpoint was overall response rate (CR + partial response ("PR")).

Patients who received HITS immediately after induction had higher response rates (47% vs. 18%) and superior estimated 3-year overall survival (85% vs. 29%) compared with those who received the same combination regimen later in the course of treatment. Safety results showed that the findings were consistent with previous studies for naxitamab and HITS. The HITS combination did not appear to exacerbate the rate nor the intensity of infusion-related toxicities of naxitamab when observed as a stand-alone treatment.

"These results suggest that the combination of naxitamab and chemotherapy, when promptly initiated in patients with an incomplete EOI response, can overcome chemoresistance," said Dr. Jaume Mora, the study's principal investigator at Sant Joan de Déu Barcelona Children's Hospital. "By contrast, a profound resistance may develop in patients administered additional treatment before receiving HITS, underscoring the need to initiate the naxitamab-based chemo-immunotherapy as early as possible."

For more information on this critical development in the treatment paradigm for patients with high-risk neuroblastoma, the online publication is available here.

Researchers at Memorial Sloan Kettering Cancer Center (MSK) developed DANYELZA® (naxitamab-gqgk), which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests in 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 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 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, OMBLASTYS® (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 Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about our business model, including the Company's plans and strategies, development, commercialization and product distribution plans; expectations with respect to our products and product candidates, including the potential of DANYELZA and the potential benefits thereof; 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", "guidance," 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 macroeconomic conditions, including the conflict between Russia and Ukraine and sanctions related thereto, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and future

filings and reports by the Company. 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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