Y-mAbs Announces Update to National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for Neuroblastoma to Include Naxitamab-gqgk (DANYELZA®)

May 7, 2025

PRINCETON, N.J., May 07, 2025 (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 radioimmunotherapy and antibody-based therapeutic products for the treatment of cancer, today announced that naxitamab-gqgk (DANYELZA®) is recommended by the National Comprehensive Cancer Network® (“NCCN”) Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) as a NCCN Category 2A treatment option for high-risk neuroblastoma.

“We are very pleased with NCCN’s update of the NCCN Guidelines to include naxitamab-gggk (DANYELZA). We believe this decision reinforces the importance of naxitimab-gggk (DANYELZA) as a leading anti-GD2 therapy of choice for physicians treating patients with relapsed/refractory high-risk neuroblastoma,” said Doug Gentilcore, SVP, DANYELZA Business Unit Head.

Naxitamab-gqgk (DANYELZA) was granted accelerated approval by the U.S. Food and Drug Administration (“FDA”) on November 25, 2020 in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) for pediatric patients one year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy. The FDA approval of naxitamab-gqgk (DANYELZA) was based on efficacy results in patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow enrolled in two single-arm, open-label trials: Study 201 (NCT 03363373) and Study 12-230 (NCT 01757626).

The NCCN is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to defining and advancing quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed naxitamab-gqgk (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 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 here.

DANYELZA is currently not approved for the treatment of osteosarcoma in any jurisdiction.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, radioimmunotherapy and antibody-based therapeutic cancer products. The Company’s technologies include its investigational Self-Assembly DisAssembly (“SADA”) Pretargeted Radioimmunotherapy Platform (“PRIT”) and bispecific antibodies generated using the Y-BiClone platform. The Company’s broad and advanced product pipeline includes the anti-GD2 therapy DANYELZA® (naxitamab-gqgk), the first FDA-approved treatment for patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow after a partial response, minor response, or stable disease to prior therapy.

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 financial outlook for 2025 and beyond, including estimated operating expenses, use of cash and cash equivalents and DANYELZA product revenue and sufficiency of cash resources and related assumptions; expectations with respect to the Company’s future financial performance; implied and express statements regarding the future of the Company’s business, including with respect to expansion and its goals; expectations with respect to the Company’s plans and strategies, development, regulatory, commercialization and product distribution plans, including the timing thereof; expectations with respect to the Company’s products and product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA PRIT technology and potential benefits and applications thereof; expectations relating to key anticipated development milestones, including potential expansion and advancement of commercialization and development efforts, including potential indications, applications and geographies, and the timing thereof; expectations with respect to current and future clinical and pre-clinical studies and the Company’s research and development programs, including with respect to timing and results; expectations regarding collaborations or strategic partnerships 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,” “goal,” “objective,” 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 the Company's financial condition and need for additional capital; the risks that actual results of the Company's restructuring plan and revised business plan will not be as expected; risks associated with the Company's development work; cost and success of the Company's product development activities and clinical trials; the risks of delay in the timing of the Company's or its partners' regulatory submissions or failure to receive approval of its drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of product candidates; development of sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for products; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture as well as regulatory submissions; the Company's ability to enter into new partnerships or to recognize the anticipated benefits from its existing partnerships; risks related to government regulation; risks related to market approval, risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's common stock, risks associated with macroeconomic conditions, including the conflict between Russia and Ukraine and sanctions related thereto, the state of war between Israel and Hamas and the related risk of a larger regional conflict, 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 ended December 31, 2024, and the Company's Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2024, and September 30, 2024, 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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Source: Y-mAbs Therapeutics, Inc.