# Y-mAbs and Nobelpharma Announce Exclusive License and Distribution Agreement for DANYELZA® (naxitamab-gqgk) in Japan

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NEW YORK, Nov. 04, 2024 (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, and Nobelpharma Co., Ltd. today announced that they have entered into an exclusive license and distribution agreement for the development and commercialization in Japan of DANYELZA for the treatment of patients with relapsed/refractory high-risk neuroblastoma and, upon agreement by the parties, potentially relapsed osteosarcoma.

Under the terms of the agreement, Nobelpharma will employ its regulatory, marketing, sales and access expertise to carry out development work and to submit DANYELZA for approval by Japanese regulatory authorities, and to market, sell, and distribute DANYELZA in Japan, if approved. Pursuant to the agreement, Y-mAbs will receive an upfront payment of $2.0 million from Nobelpharma in connection with entering into the agreement and is entitled to receive up to $31.0 million in product and commercial milestone payments in addition to profit sharing on commercial sales on DANYELZA, if successfully approved and commercialized in Japan.

"Our exclusive license and distribution agreement with Nobelpharma in Japan is an important step in our continued global expansion efforts of DANYELZA," said Michael Rossi, President and Chief Executive Officer of Y-mAbs. "If approved in the region, we believe DANYELZA can deliver a meaningful impact to patients in Japan fighting relapsed/refractory high-risk neuroblastoma and improve long-term quality of life for these children."

"We believe that Nobelpharma is the right partner for Y-mAbs in Japan, and we are excited to work with Nobelpharma towards the potential approval and commercial launch of DANYELZA in the region," said Thomas Gad, Founder and Chief Business Officer of Y-mAbs. "DANYELZA, if approved in Japan for relapsed/refractory high-risk neuroblastoma, will provide a new out-patient anti-GD2 therapeutic option for physicians in the treatment of children facing this advanced form of pediatric cancer. We remain steadfast in our commitment to provide access to DANYELZA and improve the lives of children and families around the globe facing advanced cancers."

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.

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 expectations relating to the Company's partnership with Nobelpharma, including the development process and regulatory submissions with respect to the potential approval and commercialization of DANYELZA in Japan and the potential indications thereof; the receipt by the Company of any payments or royalties from Nobelpharma; 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 reliance on a third-party for development work associated with the regulatory process with respect to and potential commercialization of DANYELZA in Japan; cost and success of the Company's and Nobelpharma's product development activities and clinical trials; the risks of delay in the timing of the Company's and Nobelpharma's regulatory submissions or failure to receive approval of DANYELZA in Japan; and the risks related to commercializing any approved pharmaceutical product in a territory, including with respect to the rate and degree of market acceptance. All statements are subject to the risks described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2024 and June 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.

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

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