Y-mAbs and Takeda Announces Marketing Authorization in Israel for DANYELZA® (naxitamab-gqgk) for Neuroblastoma

August 30, 2022

NEW YORK and PETAH TIKVA, Israel, Aug. 30, 2022 (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 and Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (TSE:4502/NSY:TAK) ("Takeda"), announced today that the Israeli Ministry of Health has approved DANYELZA in Israel for the treatment, in combination with granulocyte-macrophage colony-stimulating factor (“GM-CSF”), 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.

In Israel, DANYELZA is expected to be commercialized by Takeda Israel, under the exclusive license and distribution agreement entered in 2020 between Takeda Israel and the Company.

“The regulatory approval of DANYELZA in Israel represents our first marketing authorization outside of the U.S. and is a milestone for our collaboration with Takeda and more importantly for the pediatric patients we are dedicated to serving,” said Thomas Gad, President, and Interim Chief Executive Officer. “The approval in Israel further demonstrates our commitment to expanding the reach of our commercial stage products internationally to patients with unmet medical needs.”

“We are extremely excited by the approval of DANYELZA in Israel,” said Arie Kramer, General Manager of Takeda Israel. “This registration, following the expedited reimbursement of the product last December by the Israeli Ministry of Health, allowing Takeda and Y-mAbs to offer a new innovative treatment for pediatric neuroblastoma patients in Israel, is in alignment with Takeda’s vision of Better Health and Brighter Future to every patient in the world.”

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the compound.

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 at the registration-stage, omburtamab, which targets tumors that express B7-3.

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,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 regarding expected commercializtion of DANYELZA in Israel by Takeda, our commitment to expanding the reach of our commercial stage products internationally to patients with unmet medical needs, statements about our business model and development, commercialization and product 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”, “goal,” “aim,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Our products, 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 COVID-19 pandemic, risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, 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, 2021, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, 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 except as required by law.

About Takeda Israel

Takeda Israel Ltd, is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK), which is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (“GI”). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. Takeda is focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries.

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For more information, visit https://www.takeda.com.

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