UPDATE - Y-mAbs Announces Pipeline Update

December 15, 2021

NEW YORK, Dec. 15, 2021 (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 clinical experience for naxitamab and data from the Company’s SADA technology programs will be presented at the Company’s R&D event, which will take place virtually today at 12 p.m. Eastern Time.

Investors, analysts, members of the media and public may access the event via a live webcast.

The Y-mAbs research and development day will feature presentations from oncology key opinion leaders (“KOLs”) Javier E. Oesterheld, M.D. (Atrium Health) and Jaume Mora, M.D., Ph.D. (SJD Barcelona Children's Hospital). An update on Y-mAbs’ broad and advanced product pipeline, including the Company's SADA Technology, will follow from Vignesh Rajah, MBBS, DCH, MRCP(UK), MBA, (SVP, Chief Medical Officer at Y-mAbs) and Steen Lisby, M.D., DMSc, (SVP, Chief Scientific Officer at Y-mAbs).

SADA Technology

Dr. Lisby will present new details on the proposed mechanism of action for the SADA Technology. The Company plans to file an Investigational New Drug Application (“IND”) with the US Food & Drug Administration (“FDA”) for GD2-SADA by the end of this year.

Naxitamab

Dr. Mora, who has experience treating neuroblastoma patients with both naxitamab and a competing anti-GD2 antibody, will present compassionate use data regarding an investigational infusion protocol for naxitamab, systematically increasing the infusion rate during the treatment. Using the revised infusion rate, for which a provisional patent application has been filed by Y-mAbs and the co-inventors Jaume Mora from SJD Barcelona Children's Hospital and Dr. Nai-Kong Cheung, MD, PhD, and Shakeel Modak, MD, both from Memorial Sloan Kettering Cancer Center (“MSK”) in New York, it was observed that the protocol may help with managing Grade 3 and Grade 4 adverse events.

DANYELZA® (naxitamab-gqgk)

Dr. Oesterheld will present his personal experience from Levine Children’s Hospital after several patient treatment experiences with DANYELZA® (naxitamab-gqgk).

“I am delighted to see that the efforts led by Dr. Mora and supported by Y-mAbs as well as Dr. Cheung and Dr. Modak from MSK has led to what we believe may be a significant discovery. After years of experience in the clinic, we believe that Dr. Mora’s method of managing the infusion rate of naxitamab now potentially may open up the use of naxitamab for a wide range of GD2 positive indications, such as breast cancer, melanoma, sarcomas, small-cell lung cancer and other cancers, for which we can now consider planning Phase 2 studies,” said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, “We are excited to share these new updates on both our naxitamab program and the SADA Technology. We believe that the prospects for the SADA Technology which combines antibodies and radioactive payloads are highly encouraging and could potentially revolutionize many cancer treatments known today.”

Researchers at MSK developed naxitamab and the SADA Technology, which are exclusively licensed by MSK to Y-mAbs. As a result of these licensing arrangements, MSK has institutional financial interest related to the compound and technology and Y-mAbs.

About DANYELZA® (naxitamab-gqgk)

DANYELZA 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, anaphylaxis, hypotension, bronchospasm and stridor and neurotoxicity, such as severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome. 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 products for the treatment of cancer. The Company has a broad and advanced product pipeline, including one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, 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 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’’ 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; 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 pandemic caused by the coronavirus known as COVID-19 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, 2020 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.

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

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