



Y-mAbs Announces Pipeline Update

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NEW YORK, Dec. 16, 2020 (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 data for DANYELZA® (naxitamab-gqgk), omburtamab and nivatrotamab will be presented at the Company's R&D event, which takes place virtually today at 12 p.m. Eastern Time. Key opinion leaders, including Shakeel Modak, M.D., MRCP, Memorial Sloan Kettering ("MSK"), Jaume Mora, M.D., Ph.D., SJD Barcelona Children's Hospital, and Brian H. Santich, Ph.D., MSK, will discuss the current treatment landscape and unmet medical needs for high-risk neuroblastoma, osteosarcoma and other solid tumors. Investors, analysts, members of the media and public may access the event via a live [webcast](#).

DANYELZA

Dr. Mora, who has experience treating frontline neuroblastoma patients with both DANYELZA and a competing anti-GD2 antibody, will present clinical data from both antibodies. Data from an investigator sponsored frontline study of DANYELZA comprised 73 patients with high-risk stage 4 neuroblastoma of which 55 patients were in their first complete remission ("CR") and 18 patients were in their second CR. Patients in first CR showed an overall 74.3% event free survival ("EFS") at 24 months and an overall survival ("OS") of 91.6% at 24 months. Patients in second CR showed an overall 38.5% EFS at 24 months and an OS of 88.1% at 24 months.

In osteosarcoma, the Company will present an update on its ongoing Phase 2 study, which started more than 4 years ago at MSK and has now been approved for recruitment at two other U.S. sites. A total of 33 patients have received DANYELZA. At 30 months of follow-up the EFS was in excess of 50%.

Omburtamab

The company will also reconfirm its plan to resubmit its omburtamab BLA for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma to the FDA in the beginning of 2021. Preliminary Overall Survival ("OS") data for the Company's multicenter Study 101 for the first 18 months appears supportive of the conclusion from an earlier Study 03-133 at MSK on survival improvement for these patients, with 75% of patients surviving after 18 months. Additionally, the preliminary propensity score analysis of Study 03-133 compared to external control subjects, shows a significant difference in three years overall survival ($p < 0.001$). Finally, an independent radiographic evaluation of the tumor responses in Study 101, shows that for ten evaluable patients with measurable disease, a total of 40% of the patients responded to omburtamab, 20% with complete response ("CR") and 20% with partial response ("PR"), and another five patients had stable disease ("SD"). All nine patients with response or SD maintained these at six months follow up.

Nivatrotamab

The Company will also present a status on Study 18-034, covering the first six cohorts of the study, where patients have received up to 8 µg/kg per dose. A total of ten patients were enrolled in the study. In this initial part of the study, no CRs or PRs were achieved, but the Company is preparing for the Phase 2 studies, including a separate multicenter study in small cell lung cancer. Future protocols will be amended to subcutaneous administration, more frequent dose exposure and, in addition, the premedication regime will be altered with the objective of being able to further increase doses of nivatrotamab.

"I am delighted and excited to welcome this excellent group of key opinion leaders to our R&D event. It will be a great opportunity to learn more about the clinical experience of DANYELZA, omburtamab and nivatrotamab, also noting that SJD Barcelona Children's Hospital, a major pediatric center located in Barcelona, Spain, has produced promising frontline DANYELZA data," said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, "We are excited to share this broad update on our pipeline and believe this to be class leading clinical results. The tumor response data for omburtamab paves the way for the resubmission of the BLA in early 2021."

Researchers at MSK developed DANYELZA, omburtamab and nivatrotamab, which are exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests related to the compounds 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, 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 and commercialization plans; the benefits, safety and efficacy of DANYELZA, 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," "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 novel 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 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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