Y-mAbs' Announces Clearance of IND for GD2-SADA

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NEW YORK, July 12, 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, today announced initiation of its first clinical trial with a SADA construct. This Phase 1 multicenter basket trial targets malignant melanoma, sarcoma and small cell lung cancer. The trial will have three parts: Part A with dose-finding for the SADA molecule and testing of dosing intervals between the protein and the ^{177}Lu-DOTA payload, Part B will determine the optimal dose of ^{177}Lu-DOTA, and Part C will be evaluating safety and initial signals of efficacy using repeated dosing. The Company expects a total of approximately 59 patients at 6-10 U.S. sites to be included in the trial.

The GD2-SADA construct was created using our SADA technology, which was licensed by the Company from Memorial Sloan Kettering Cancer Center ("MSK") and Massachusetts Institute of Technology ("MIT") in April 2020. The SADA technology utilizes a pre-targeted payload delivery method where antibody constructs assemble in tetramers and bind to the tumor target. Unbound constructs predictably disassemble into smaller antibody fragments and are excreted through the kidneys within hours after administration. In a second infusion, a radioactive payload binds to the antibody constructs attached to the tumor target in order to radiate the tumor. This provides the possibility of targeting tumors with precision while minimizing radiation of normal tissues. We believe that the SADA technology platform can deliver a variety of payloads and could potentially be developed against multiple tumor targets, as well as for theragnostic purposes.

"The FDA acceptance of the IND for GD2-SADA marks an important milestone towards our mission of developing novel SADA treatments as we continue to execute our clinical development strategy for our pipeline of SADA constructs for the treatment of cancers with unmet medical need," said Thomas Gad, founder, President and Interim CEO. "We are seeing significant partnership interest for the SADA technology and we believe we are well-positioned to leverage the SADA platform as we move forward. We are truly excited about the potential of the SADA technology, which has already shown great promise, and we believe that it can further unlock the potential of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents."

Researchers at MSK, including Dr. Cheung, developed the SADA technology for radioimmunotherapy, which is exclusively licensed by MSK to Y-mAbs. Dr. Cheung has intellectual property rights and interests in the technology, and as a result of this licensing arrangement, MSK has institutional financial interests in the technology and in Y-mAbs.

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, OMBLASTYS® (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 its variants such as Delta and Omicron, risks associated with Russia's recent invasion of Ukraine 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 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.

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