# Y-mAbs Provides Strategic Business Update and 2025 Priorities

January 10, 2025

*Company establishes two business units with goal of accelerating the advancement of its Radiopharmaceuticals Platform and optimizing the commercial potential of DANYELZA*

*Preliminary Part A data from GD2-SADA Phase 1 trial demonstrates tolerability and validity of SADA PRIT platform pre-targeting approach; Company expects to present Part A data in the second quarter of 2025*

*Company reports preliminary estimated unaudited Total Net Revenue of approximately $88 million for the year ended December 31, 2024, within Full Year 2024 top line guidance range*

*Company reports preliminary estimated unaudited cash, cash equivalents and marketable securities of approximately $67 million as of December 31, 2024, anticipated to support operations into 2027*

*Company presenting at 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2024 at 5:15 p.m. PT*

NEW YORK, Jan. 10, 2025 (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, today announced strategic business updates and 2025 priorities in the Company's mission to improve and extend people's lives.

**Business Update**

Y-mAbs is internally realigning operations with the establishment of two business units: Radiopharmaceuticals and DANYELZA.

- Radiopharmaceuticals
  - Novel Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy ("SADA PRIT") platform designed to improve upon traditional radioimmunotherapy by delivering high therapeutic dose while minimizing off-target exposure, increase physician participation and decrease manufacturing and infrastructure costs.
  - SADA PRIT technology utilizes a pre-targeted payload delivery method where antibody constructs assemble in tetramers and bind to the tumor target.
  - Platform can deliver a variety of payloads and could potentially be developed against multiple tumor targets, as well as for radiopharmaceutical purposes.
  - Y-mAbs is currently evaluating its SADA PRIT technology in two clinical trials in the U.S.
- DANYELZA
  - DANYELZA is a GD2 antibody and the only FDA-approved treatment for the treatment of patients one-year of age and older with high-risk relapsed/refractory neuroblastoma in the bone and bone marrow.
  - Initially commercially launched in 2021, DANYELZA is commercialized across both U.S. and international markets.

The business realignment is designed to support the optimization of internal resources and provide flexibility and agility to advance the Company's novel SADA PRIT platform programs through clinical development while simultaneously driving commercial growth of DANYELZA.

"Our mission at Y-mAbs has been clear from day one: bring important new cancer therapies to patients as quickly as possible. Since the successful commercial launch of DANYELZA, we are proud to have positively impacted the lives of children with high-risk relapsed/refractory neuroblastoma, giving the hope of a better future to families around the world," said Michael Rossi, President and Chief Executive Officer. "As we look ahead to the potential of our novel Radiopharmaceutical platform and high value therapeutic areas, as well as the potential of DANYELZA, we believe now is the right time to focus our efforts in two business units. By doing so, we expect to expand our radiopharmaceutical capabilities, accelerate clinical execution, further improve capital efficiencies, and better align strategic priorities."

With these updates to the business strategy, Y-mAbs anticipates a reduction in its current workforce of up to approximately 13%,depending on whether a portion of impacted employees accept newly created positions, and intends to move some roles from Denmark to the U.S. to more efficiently coordinate the advancement of its radiopharmaceutical platform, with a small adjustment of the DANYELZA commercial team to focus the team around potential growth opportunities within the anti-GD2 market.

**Recent Pipeline Advancement**

**GD2-SADA (Trial 1001):** Y-mAbs has dosed 21 patients at six sites to date in Part A of the GD2-SADA Phase 1 trial in adults with solid tumors. Tumor types include small cell lung cancer (SCLC), malignant melanoma, sarcomas and adult neuroblastoma. Preliminary data from the Part A GD2-SADA Phase 1 trial has demonstrated this novel pre-targeting approach to be well-tolerated with no dose-limiting toxicities (DLTs) and no treatment-related adverse events (AEs) reported. Part A remains ongoing as the Company aggregates final data on patients in open cohorts and continues to study further patients incorporating various elements to further optimize the platform aiming to maximize tumor uptake and retention. The Company expects to share data from Part A in the second quarter of 2025.

"The preliminary data from Part A of our GD2-SADA Phase 1 trial demonstrates the viability of the pre-targeted approach of the platform. We continue to gather learnings from the 21 patients dosed to date, which we anticipate will allow us to improve tumor uptake, determine the optimal therapeutic dose, and establish the ideal construct to further advance Trial 1001 in the clinic," said Norman LaFrance, M.D., Chief Development Officer. "We

believe in the significant potential of our SADA PRIT platform, and we are excited to be at the forefront of this next-generation, pre-targeted radiotherapy technology."

**CD38-SADA (Trial 1201):** To date, six sites have been selected, and three sites have been activated. The Company expects to dose the first non-Hodgkin Lymphoma (NHL) patient in Study 1201 in the first quarter of 2025.

**Unaudited Preliminary FY2024 Results**

Y-mAbs reported preliminary estimated unaudited full year 2024 total net revenue of approximately $88 million, within the Company's previously announced guidance range of between $87 million and $91 million, and preliminary estimated unaudited cash, cash equivalents and marketable securities as of December 31, 2024 of approximately $67 million, with preliminary estimated total cash investment for the full year 2024 of approximately $11 million, which is below the Company's guidance range of between $15 million and $20 million.

**Anticipated 2025 Milestones**

- Part A data from GD2-SADA Phase 1 trial (Trial 1001) expected to be presented in the second quarter of 2025
- GD2-SADA optimization data expected to be presented in the second quarter of 2025
- Expect to present updates with respect to reprioritized SADA PRIT pipeline, including new high-value target indications and timelines, in the second quarter of 2025
- Expect to dose first patient in CD38-SADA Phase 1 trial (Trial 1201) in the first quarter of 2025
- Potential for marketing approval of DANYELZA in new ex-U.S. market in 2025
- Plan to provide full year 2025 guidance in conjunction with full year 2024 earnings report in the first quarter of 2025

**Upcoming Investor Presentation**

The company previously announced that Mr. Rossi will present at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, CA on Wednesday, January 15, 2025 at 5:15 p.m. PT. A live webcast will be available under the Events section of the Company's investor relations website at ir.ymabs.com. The webcast will be archived and available for replay for 30 days after the event.

**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 The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about: our business model, expectations with respect to estimated charges and expenses in connection with the business realignment plan, including the amounts and timing thereof, preliminary estimated financial results and expectations for the year ended December 31, 2024, including estimated operating expenses, cash and cash equivalents and net revenue; the realignment plan, including the reduction in workforce and operations and resources, and the expected impacts, anticipated expenses and benefits thereof, including operational flexibility and acceleration of clinical development within the radiopharmaceutical platform; implied and express statements regarding the future of the Company's business; the Company's strategies, development, regulatory, commercialization and product distribution plans; expectations with respect to the Company's products and product candidates, including market access expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA PRIT technology platform and product candidates based on such technology; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA and the SADA PRIT technology, including anticipated collection and presentation of data, and the timing thereof; 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; and other statements that are not historical facts. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "guidance," "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; the risk that our reported results may differ materially from our preliminary estimated operating expense, cash and cash equivalent and DANYELZA net product revenue results as a result of the completion of year-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized; the risks that actual results of the business realignment plan will not be as expected, including the impact on employees and other parties; 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; risks related to our ability 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 ongoing geopolitical conflicts; 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, 2023, our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30, and September 30, 2024, 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.



**Investor Contact:**
Courtney Dugan

VP, Head of Investor Relations
cdu@ymabs.com

Source: Y-mAbs Therapeutics, Inc.