

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 28, 2025

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38650
(Commission
File Number)

47-4619612
(I.R.S. Employer
Identification No.)

202 Carnegie Center
Suite 301
Princeton, New Jersey 08540
(Address of principal executive offices) (Zip Code)

(646) 885-8505
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:
Common Stock, \$0.0001 par value

Trading Symbol
YMAB

Name of each exchange on which registered
NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 7.01 REGULATION FD DISCLOSURE.

On May 28, 2025, Y-mAbs Therapeutics, Inc. (the “Company”) is holding a virtual research and development update (the “R&D Update”) regarding progress across its Radiopharmaceutical business unit. A copy of the slide presentation is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K is being furnished to the Securities and Exchange Commission and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

ITEM 8.01 OTHER EVENTS.

In connection with the R&D Update, on May 28, 2025, the Company issued a press release discussing complete Part A data from its GD2-Self-Assembly DisAssembly (“SADA”) Phase 1 Clinical Trial (Trial 1001) as well as its strategy for development of its SADA program. The full text of the Company’s press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation, dated May 28, 2025.
99.2	Press Release, dated May 28, 2025, issued by Y-mAbs Therapeutics, Inc.
104	Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: May 28, 2025

By: /s/ Michael Rossi
Michael Rossi
President and Chief Executive Officer



Radiopharmaceutical R&D Update

May 28, 2025





Disclaimer

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the US Private Securities Litigation Reform Act of 1995. The forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," "goal," "objective," "guidance," "aim," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements include, but are not limited to, statements about pre-clinical and clinical data, regulatory matters, clinical trial timing and plans, the achievement of clinical and commercial milestones, the potential benefits of the Company's programs and product candidates, and other statements that are not historical facts. 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 actual results of the Company's business unit realignment will not be as expected; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials including if we encounter difficulties enrolling patients in our clinical trials; the risks of delays in FDA and/or EU approval of our drug candidates or failure to receive approval; the risks related to commercializing any approved new 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; risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; our ability to enter into collaboration or other arrangements with partners; risks associated with protection of our intellectual property rights; risks associated with macroeconomic conditions, including the conflict between Russia and Ukraine and Israel and Hamas and sanctions related thereto, international trade policies, including tariffs and trade restrictions, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; 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 fiscal year ended December 31, 2024 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, in addition to other reports the Company files from time to time with the Securities and Exchange Commission. Any forward-looking statements contained in this presentation 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.



Today's Presenters



Mike Rossi
President and
Chief Executive Officer



Natalie Tucker
SVP, Radiopharmaceutical
Business Unit Head



Norman LaFrance, MD
Chief Medical and
Development Officer

Additional Team Members Available During Q&A

Y-mAbs is a Commercial Biopharmaceutical Company with Two Distinct Business Units: DANYELZA and Radiopharmaceuticals



DANYELZA



RADIOPHARMACEUTICALS





Our VISION for GROWTH

- ☆ Deliver on Promise of Radiopharmaceuticals with Minimal Off-Target Effects
- ☆ Fully Operational Theranostic Platform
- ☆ Proprietary Radiohaptens Enabling Multiple Isotope Modularity
- ☆ Investment Favors Development, NOT CAPEX
- ☆ Physician Participation Along the Treatment Journey

We are Positioned to Potentially Disrupt the Existing Approach to Radiopharmaceuticals by Addressing Key Obstacles that Limit Commercial Utilization



Leverage Existing Infrastructure

- Assembly occurs in vivo
- Reduced COGS and overhead



Enhance Physician Participation

- Allows for surround sound participation from Oncologist and RadOnc/NM



Patient-Centric Targeting

- Modular design enables isotope flexibility
- Dosing scalability



Improved Patient Safety

- Potential for optimal therapeutic dose with minimal toxicity

Radiopharmaceuticals: Multiple Potential High Value Inflection Points Anticipated Ahead

Increasing commitment, capabilities, and leadership in Radiopharmaceuticals

2024	2025	2026	2027
<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Increased organizational focus on Radiopharmaceuticals <input checked="" type="checkbox"/> New Executive Team appointed with deep Radiopharma expertise 	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Realignment into two business units: DANYELZA and Radiopharmaceuticals <input checked="" type="checkbox"/> CD38-SADA FPI in 1H 2025 <input checked="" type="checkbox"/> GD2-SADA Trial 1001 Part A Data Readout <input type="checkbox"/> GD2-Diagnostic IND Submission in 2H 2025 	<ul style="list-style-type: none"> <input type="checkbox"/> GD2-Diagnostic FPI 1H 2026 <input type="checkbox"/> GD2-SADA 1001 IND Amendment* 1H 2026 <input type="checkbox"/> Initiate GD2-SADA Bridge Study with new Radiohaptens in 1H 2026 <input type="checkbox"/> Trial 1001 Bridge Study Data Readout with new Radiohaptens in 2H 2026 	<ul style="list-style-type: none"> <input type="checkbox"/> Initiate Dose Escalation Study (Trial 1001, Part B) in 1H 2027 <input type="checkbox"/> Initiation of GD2-SADA Pediatric Study (Trial 1002) in 1H 2027 <input type="checkbox"/> GD2-SADA Pediatric Trial (Trial 1002) Data Readout in 2H 2027 <input type="checkbox"/> GD2-SADA Dose Escalation Study (Trial 1001, Part B) Data Readout in 2H 2027 <input type="checkbox"/> NEW TARGET: IND submission (mCRC) in 1H 2027 <input type="checkbox"/> NEW TARGET: FPI New Therapeutic (mCRC) 2H 2027

* New IND vs Amendment pending FDA feedback; recommendation for new IND may incur delay of 2-3 months



Today's Agenda: Three Key Radiopharmaceutical Updates





Recent Insights Will Be Scaled Across the Platform

1

Met primary objective demonstrating GD2-SADA-¹⁷⁷Lu-DOTA is safe and well tolerated

2

GD2-SADA PK was predicted and with close interpatient cohort repeatability

3

Identified opportunities to streamline study designs and improve operations to accelerate future trials

4

Study insights will benefit entire platform and support strategic advancement of high-value targets



Today's Agenda: Three Key Radiopharmaceutical Updates

1. Trial 1001 Part A – Complete

2. Key Learnings from Molecule Optimization Studies

3. Expanded Development Pipeline

**Y-mAbs
Development**

GD2-SADA Trial 1001 Phase 1 Clinical Trial Background

GD2-SADA Phase 1 Trial 1001, Part A: Study Objectives and Design

Objectives

- **Primary:** Establish safety of GD2-SADA
- **Secondary:** Evaluate dosimetry, PK, and immunogenicity profiles of GD2-SADA-¹⁷⁷Lu-DOTA

Trial 1001 Details

Part A

Eligible Indications

- HR-NB (≥16 y.o.)
- SCLC (aged ≥18 y.o.)
- Sarcoma (aged ≥16 y.o.)
- Melanoma (aged ≥18 y.o.)

Key Eligibility Criteria

- Recurrent or refractory metastatic solid tumors
- Measurable/evaluable disease
- ECOG 0 or 1
- Adequate liver, renal, and hematological function and no serious intercurrent illness
- No prior systemic treatment within 3 wks of 1st dose

Cohort Design (7 clinical trial sites)

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6
GD2-SADA	0.3 mg/kg	0.3 mg/kg	1 mg/kg	3 mg/kg	1 mg/kg	1 mg/kg
Interval (days)	5	2	5	5	4	3

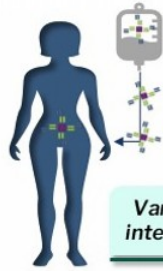
Part A Treatment Regimen Was Based on Tumors Selected by CT and Included an Imaging Stage Followed by a Treatment Stage

Imaging Stage: Tumor Uptake, PK, Dosimetry Assessment

Therapeutic Stage: 100 or 200 mCi ^{177}Lu -DOTA

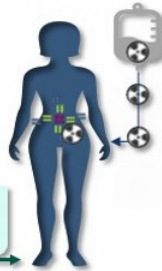


Pre-Imaging
Lesion selection
via CT scan
(up to 5 selected)

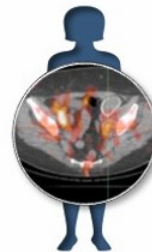


Day 1
GD2-SADA Protein
0.3, 1.0, or 3.0 mg/kg

Varying clearance
interval of 2-5 days

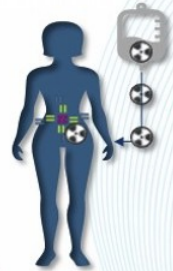


Day 3+
 ^{177}Lu -DOTA
30 mCi



Nuclear Imaging
Determination of tumor
uptake (in 5 prev. selected)

Positive tumor
uptake

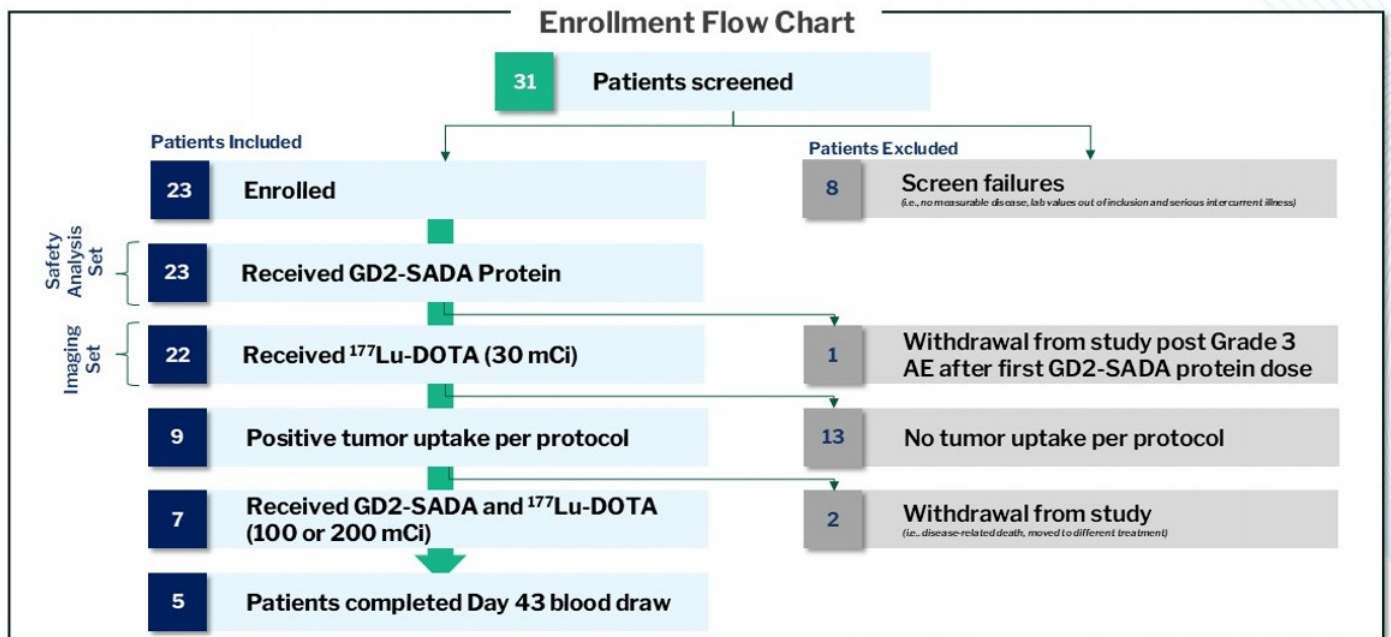


Day 15+
GD2-SADA (same
concentration) and
 ^{177}Lu -DOTA (100 or 200
mCi) with same clearance
interval

Blood was collected at serial timepoints to assess GD2-SADA and ^{177}Lu -DOTA PK and GD2-SADA immunogenicity

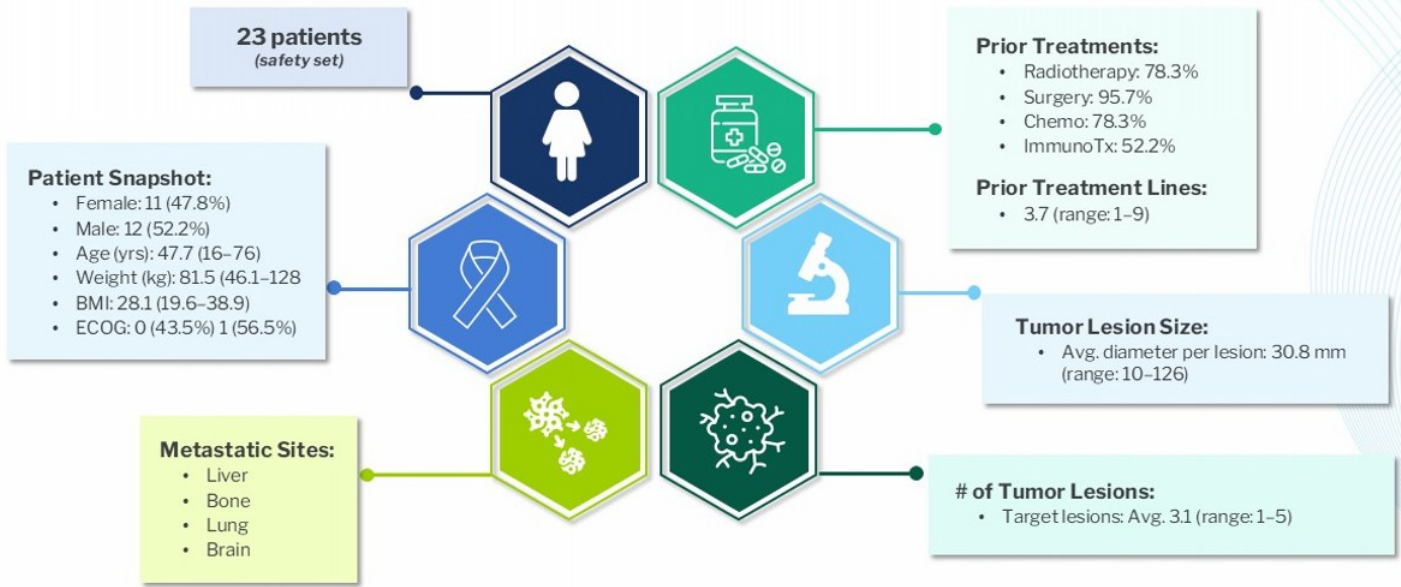
Patient Demographics

A Total of 22 Patients Were Treated with the GD2-SADA-¹⁷⁷Lu-DOTA Complex



Source Program: t_disp.sas - output t_disp.rtf - executed: 26FEB2025

Patients Were Heavily Pretreated and Similarly Distributed Across Cohorts



N: Number of patients, BMI: Body mass index, ECOG: Eastern Cooperative Oncology Group Performance Status Scale, SCLC: Small-Cell Lung Cancer
Non-Target lesions defined per RESIST Protocol
Program: t_demog.sas - output: t_demog.rtf - executed: 24APR2025 - data cutoff 22APR2025

9 Patients in the Imaging Stage Showed Positive Tumor Uptake Per Protocol Design and Were Eligible for Treatment Stage

Overview of patients who showed tumor uptake

	Cohort 2 (2-day interval)	Cohort 3 (5-day interval)	Cohort 3 (5-day interval)	Cohort 3 (5-day interval)	Cohort 4 (5-day interval)	Cohorts 5 (4-day interval)	Cohort 6 (3-day interval)	Cohort 6 (3-day interval)	Cohort 6 (3-day interval)
Diagnosis	Osteosarcoma	Osteosarcoma	Synovial Sarcoma	Uveal Melanoma	Leyomyosarcoma	Uveal Melanoma	Melanoma	Uveal Melanoma	Melanoma
Dose level (mg/kg)	0.3	1.0	1.0	1.0	3.0	1.0	1.0	1.0	1.0
Tumor uptake	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Tumor Uptake by Tumor Type (N = 22)	
Sarcoma All (Osteosarcoma)	4/11 (2/3)
Melanoma	5/8
Small Cell Lung Cancer (SCLC)	0/1
Neuroblastoma (NB)*	0/2

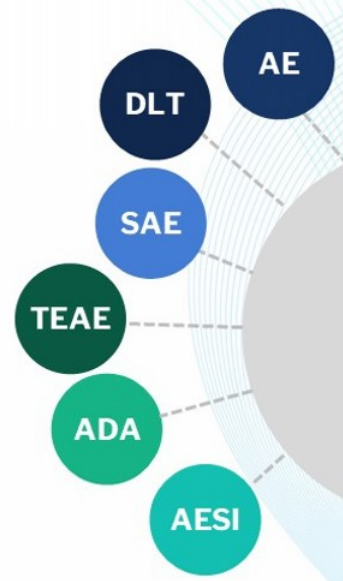
Data cut as of January 6, 2025. These early results are not complete and are not necessarily indicative of the full results or ultimate success of the SADA trials or the SADA development program which is in early development with no guaranty of approval.

* Neuroblastoma patients were >16 years old, per protocol with prior GD2 treatments

Safety Summary

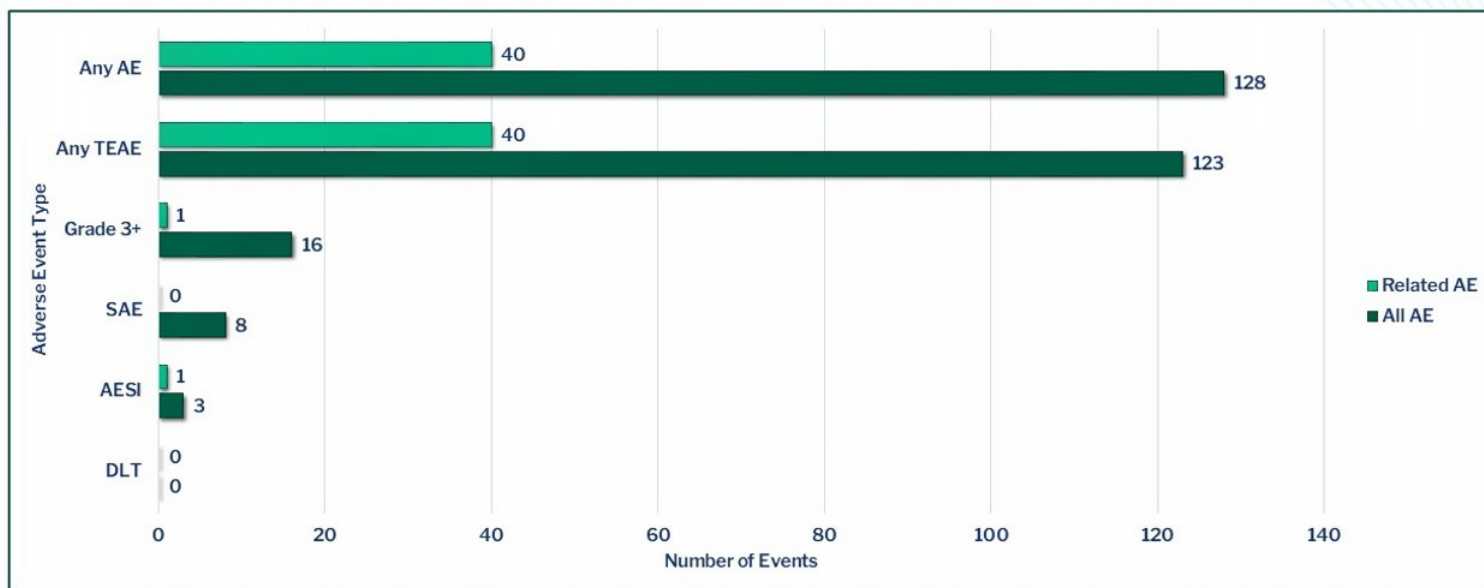
Safety Summary: Part A was Safe and Well-Tolerated Across Both GD2-SADA and ¹⁷⁷Lu-DOTA Administrations

- **No AE trends across all dosing cohorts**
 - No DLTs or treatment-related serious adverse events
 - Treatment related adverse events were mostly CTCAE grade 1 (70%) and 2 (27.5%)
 - ADA did not show conclusive evidence of immunogenicity safety risks
- **Most adverse events were lymphocyte count decrease, nausea, and constipation**
 - Most related adverse events were nausea and chills
 - No dose-dependent trends related to GD2- or radiation-related adverse events
- **Two patients reported a total of 3 AEs of Special Interest (AESI)**
 - One non-serious related event (pain)
 - Two non-related events attributed to disease progression (liver enzymes)



AE: Adverse event, TEAE: Treatment-emergent adverse event, CTCAE: Common terminology criteria for adverse events
SAE: Serious adverse event, AESI: Adverse event of special interest, DLT: Dose-limiting toxicity, ADA: Anti-drug antibodies
Related AEs are either 'Possibly' or 'Probably' related to trial drug

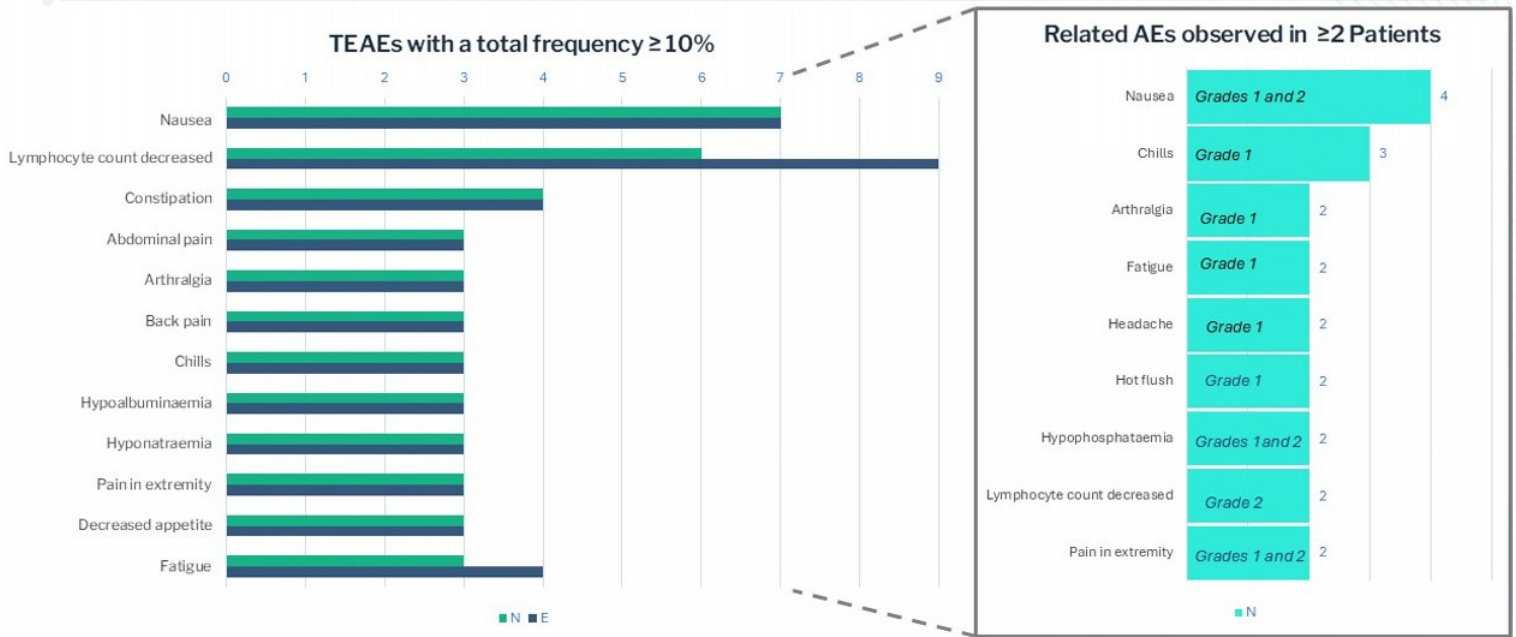
Manageable Safety Profile: No DLTs, No Treatment-related SAEs



TEAE: Treatment-emergent adverse event
Grade 3+: Common terminology criteria for adverse events (CTCAE) Grade 3 or higher
SAE: Serious adverse event
AESI: Adverse event of special interest
DLT: Dose-limiting toxicity
Related AEs are either 'Possibly' or 'Probably' related to trial drug

Program: t_ae.sas - output: t_ae.rtf - executed: 24APR2025 - data cutoff: 22APR2025

Nausea, Chills Were the Most Common Related Adverse Events





N: Number of patients experiencing the event at least once, E: Total number of reports of the event
 PT: Preferred term, TEAE: Treatment-emergent adverse event
 Note: Related AEs are either 'Possibly' or 'Probably' related to trial drug

Program: t_ae_soc.sas - output: t_ae_soc_tae.rtf - executed: 24APR2025 - data cutoff: 22APR2025

No Dose-Dependent AE Trends as Seen With GD2 Therapies or Radiopharmaceuticals; AESI Were Non-Serious

3 Adverse Events of Special Interest (AESI) in 2 Patients

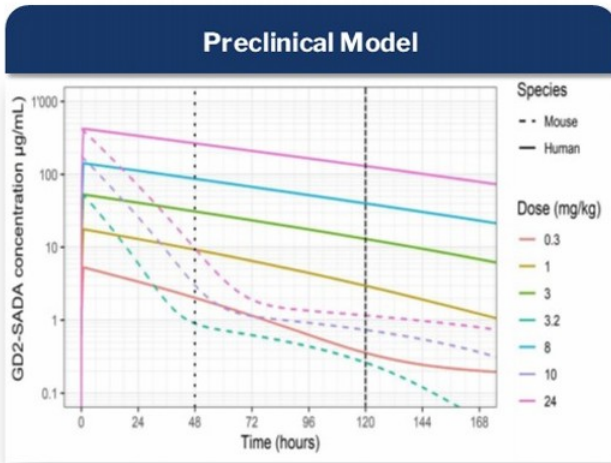
Patient 1, AESI 1: Abdominal Pain		Patient 2, AESIs 2 & 3: Liver Function			
	Cohort #	4: 3 mg/kg, 5-day interval		Cohort #	5: 1 mg/kg, 4-day interval
	History	History of cancer pain prior to GD2-SADA treatment and received concomitant medication to manage pain; also hx of diarrhea and nausea		History	Hx of elevated liver enzymes
	Presentation	Grade 3 abdominal pain day of 1 st infusion		Presentation	Elevated liver enzymes at enrollment and 1 st infusion reaching grade 3 at end of treatment visit
	Outcomes	<ul style="list-style-type: none"> Pain was non-serious and the patient recovered on the same day Patient withdrew from study and did not receive ¹⁷⁷Lu-DOTA during the Imaging Stage 		Outcomes	ALT and AST values remained high despite end of treatment
	Conclusion	With only one occurrence of related abdominal pain and no rechallenge, <i>more evidence would be needed to draw any definitive safety conclusions</i>		Conclusion	Both AESIs were serious and not recovered but not related to study drug and related to disease progression

AESI: Adverse event of special interest predefined per protocol
 AST: Aspartate Transaminase [normal range 5 - 34U/L]
 ALT: Alanine Transaminase [normal range 0 - 55U/L]
 Bilirubin [normal range 0 - 1.4mg/dL]
 Related AEs are either "Possibly" or "Probably" related to trial drug

GD2-SADA

Pharmacokinetics (PK)

Pharmacokinetics of GD2-SADA Outline the Optimal Clearance Interval for Maximum Tumor-to-Kidney Ratio

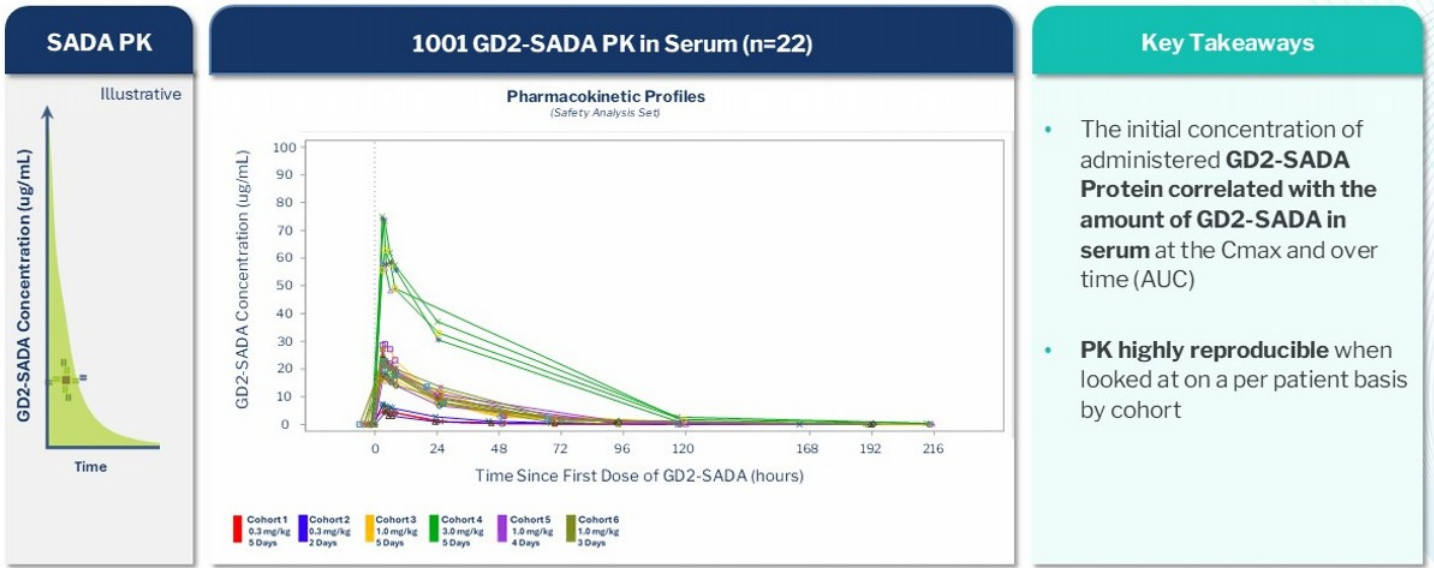


Source: "Preclinical and Translational Pharmacokinetics of GD2-SADA, a Self-Assembling and Disassembling (SADA) Bispecific Fusion Protein for Pretargeted Radioimmunotherapy (PRIT)", B.H. Santich et al., SNMMI, Nov. 2024

Key Takeaways

- **Allometric scaling** was used to model human GD2-SADA PK based on preclinical data
- **GD2-SADA blood trough was identified preclinically**, i.e., lowest amount of GD2-SADA in blood prior to ^{177}Lu -DOTA (≤ 1 $\mu\text{g/mL}$)
- **Key Learning for Trial:** Trough drives toxicity for SADA platform; similar to historic measurement of aminoglycoside trough to avoid renal toxicity

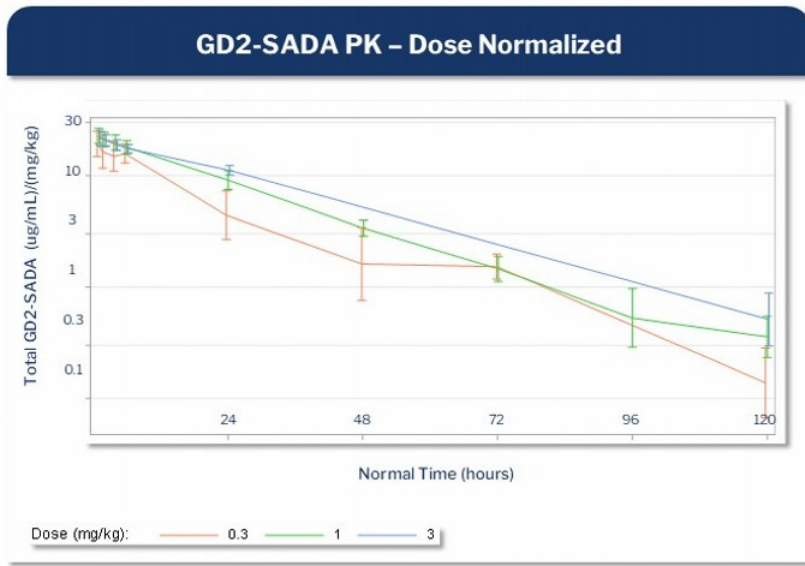
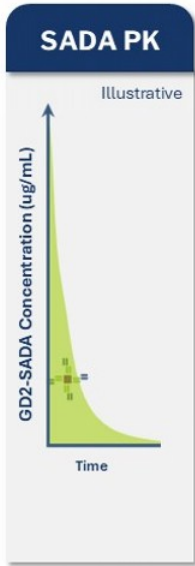
GD2-SADA Pharmacokinetics are Dose Dependent and Predictably Follow Modeling



Note: Serum levels of GD2-SADA were measured over time
N=22: One patient who withdrew prior to ¹⁷⁷Lu-DOTA administration did not continue with PK sampling

Source: Trial: Y-mAbs 1001 DMC. 06May2025

Dose Normalized GD2-SADA PK Displayed Proportional Cmax and Clearance Rates over Three Administered Dose Concentrations



Key Takeaways

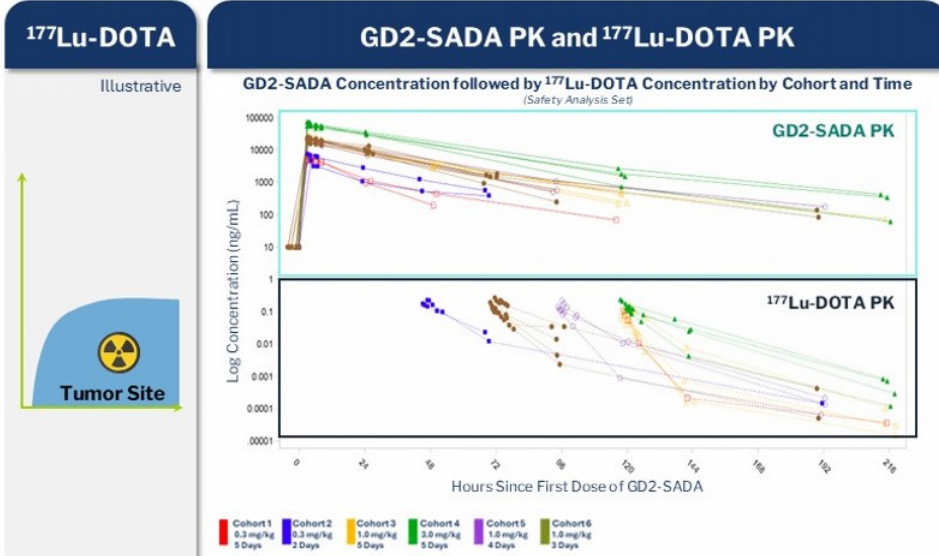
- When normalized by dose, all protein concentrations tested showed **similar clearance rates** over time
- GD2-SADA PK provides a **predictable roadmap for tailoring clearance interval** prior to isotope administration to maximize therapeutic index

Note: Serum levels of GD2-SADA were measured over time, normalized by mg/kg of GD2-SADA protein

Source: Trial: Y-mAbs 1001_f_median_sada.rtf - 05May2025

^{177}Lu -DOTA Pharmacokinetics (PK)

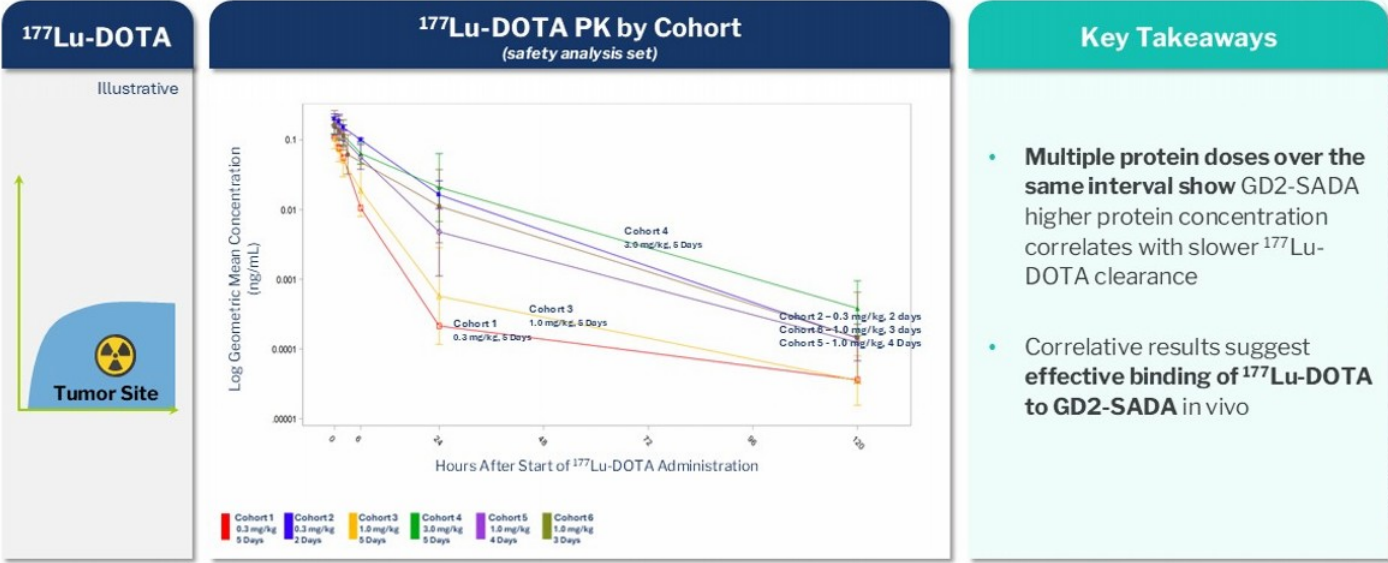
^{177}Lu -DOTA PK is a Function of the GD2-SADA Protein Concentration and Clearance Interval Allowing the Optimization of Therapeutic Index



- Key Takeaways**
- **Higher concentrations of GD2-SADA** in serum correlate with higher radioactivity levels in serum
 - This effect can be **leveraged and applied by extending intervals**
 - Understanding of PK informs clearance interval to **optimize therapeutic index**

Note: Pre-dose GD2-SADA concentration is assigned a value of 10, as it is 0 ng/mL for all included records

^{177}Lu -DOTA PK by Cohort Illustrates Dual Impact of GD2-SADA Concentration and Clearance Interval



Note: Pre-dose GD2-SADA concentration is assigned a value of 10, as it is 0 ng/mL for all included records

GD2-SADA-¹⁷⁷Lu-DOTA Dosimetry

Per Protocol, Tumor Uptake Was Restricted to Site Selected Target Lesions Identified via CT; Expanded Evaluation Included All Tumors

Per Protocol Evaluation

- ✓ Assessment of **up to 5 target lesions determined by CT** within 21 days prior to first GD2-SADA dose (measurable per RECIST 1.1)
- ✓ **Tumor uptake assessment conducted locally** 24 hours post ¹⁷⁷Lu-DOTA based on qualitative impression of contrast-to-noise ratio >3
- ✓ **Only target lesions deemed positive for uptake by the site were evaluated** for dosimetry

OLINDA/EXM[®] (dose-factor based, v1 FDA clearance 2004)

Expanded Evaluation

- ✓ Identify **all tumors (target and non-target)**, leveraging data from **SPECT/CT**
- ✓ Conduct **organ dosimetry** and **tumor dosimetry on all tumors**

Torch[®] advanced dosimetry-guided radiopharmaceutical therapy assessment software (GPU-accelerated, Full Monte Carlo dose analysis, FDA 510(k) cleared 2021)

Next generation imaging provides more insight on heterogenous tumors

Per Protocol Evaluation: 9 of 22 Patients Were Identified as Having Tumor Uptake

Analysis completed with OLINDA/EXM 2.2 Software

	Patient 003	Patient 005	Patient 008	Patient 009	Patient 011	Patient 016	Patient 018	Patient 019	Patient 021
Cohort	2	3	3	3	4	5	6	6	6
GD2-SADA protein dose (mg/kg)	0.3	1.0	1.0	1.0	3.0	1.0	1.0	1.0	1.0
Clearance Interval (days)	2	5	5	5	5	4	3	3	3
Diagnosis	Osteosarcoma	Osteosarcoma	Synovial Sarcoma	Uveal Melanoma	Leyomyosarcoma	Uveal Melanoma	Melanoma	Uveal Melanoma	Melanoma
Tumor (Gy) SPECT/CT	0.27-0.39	0.03-0.05	0.10	0.07	0.07-0.12	0.19	Pending Analysis	0.32	NA*
Kidney (Gy)	0.70	0.23	0.32	0.14	2.33	0.30	0.38	1.83	0.81
Spleen	0.28	0.01	0.25	0.12	0.08	0.24	0.30	0.68	0.20
Red Marrow (Gy)	0.04	0.01	0.03	0.01	0.02	0.03	0.01	0.07	0.02

Note: All data based on $^{30}\text{mCi}^{177}\text{LuDOTA}$ diagnostic dose; Gy represents absorbed dose
 Patient 21 (NA): Patient had tumor uptake, but lesions too close to heart for dosimetry analysis
 Patient 18 (pending analysis): data evaluation on hold, pending receipt of target lesion documentation

Per Expanded Evaluation: 16 of 22 Patients Showed Tumor Uptake, Largely Presenting with Increased Gray per Tumor

Analysis completed with Torch® Software

	Patient 003	Patient 005	Patient 008	Patient 009	Patient 011	Patient 016	Patient 018	Patient 019	Patient 021	Patient 004	Patient 006	Patient 013	Patient 014	Patient 015	Patient 017	Patient 022
Cohort	2	3	3	3	4	5	6	6	6	2	3	4	4	5	5	6
GD2-SADA protein dose (mg/kg)	0.3	1.0	1.0	1.0	3.0	1.0	1.0	1.0	1.0	0.3	1.0	3.0	3.0	1.0	1.0	1.0
Clearance Interval (days)	2	5	5	5	5	4	3	3	3	2	5	5	5	4	4	3
Diagnosis	Osteosarcoma	Osteosarcoma	Synovial Sarcoma	Uveal Melanoma	Leyomyosarcoma	Uveal Melanoma	Melanoma	Uveal Melanoma	Cutaneous Melanoma	Small Cell Lung Cancer	Pleomorphic Liposarcoma	Cutaneous Melanoma	Ewing Sarcoma	Neurosarcoma	Uveal Melanoma	Osteosarcoma
Tumor (Gy) SPECT/CT	0.40-110	0.06-0.30	0.30	0.30	0.08-0.20	0.04-0.30	0.20	0.10-0.80	Pending Analysis	0.20	0.001-0.011	0.08-0.10	0.10-0.20	0.05-0.10	0.20-0.40	0.10-1.0
Kidney (Gy)	1.0/1.5	0.30/0.10	0.30/0.30	0.30/0.40	0.90/0.80	0.2/0.2	0.20/0.20	1.70/1.80	Pending Analysis	0.80/0.80	0.01/0.01	0.6/0.50	0.30/0.40	0.30/0.30	0.20/0.20	Pending Analysis
Spleen	0.50	0.10	0.20	0.20	0.30	0.10	0.10	0.90	Pending Analysis	0.40	0.01	0.20	0.30	0.10	0.20	Pending Analysis
Lumbar Marrow (Gy)	0.20	0.07	0.10	0.10	0.01	0.08	0.04	0.03	Pending Analysis	0.20	0.002	0.10	0.20	0.10	0.20	Pending Analysis

Note: All data based on 30mCi ¹⁷⁷LuDOTA diagnostic dose; Gy represents absorbed dose; column colors represents cohorts
 Patient 21 (pending analysis): positive tumor uptake confirmed, dosimetry calculations on hold pending receipt of additional imaging data (CT scan)
 Patient 22 (pending analysis): organ analysis pending receipt of additional site images (planar/SPECT)

Per Expanded Evaluation: 16 of 22 Patients Showed Tumor Uptake, Largely Presenting with Increased Gray per Tumor

Analysis completed with Torch® Software

	Patient 003	Patient 005	Patient 008	Patient 009	Patient 011	Patient 016	Patient 018	Patient 019	Patient 021	Patient 004	Patient 006	Patient 013	Patient 014	Patient 015	Patient 017	Patient 022
Cohort	2	3	3	3	4	5	6	6	6	2	3	4	4	5	5	6
GD2-SADA protein dose (mg/kg)	0.3	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	3.0	3.0	1.0	1.0	1.0
Clearance Interval (days)	2	5	5	5	5	5	5	5	5	5	5	5	5	4	4	3
Diagnosis	Osteosarcoma	Osteosarcoma	Synovial Sarcoma	Uveal Melanoma								Cutaneous Melanoma	Ewing Sarcoma	Neurosarcoma	Uveal Melanoma	Osteosarcoma
Tumor (Gy) SPECT/CT	0.40-110	0.06-0.30	0.30	0.30								0.08-0.10	0.10-0.20	0.05-0.10	0.20-0.40	0.10-1.0
Kidney (Gy)	1.0/1.5	0.30/0.10	0.30/0.30	0.30/0.40	0.90/0.80	0.2/0.2	0.20/0.20	1.70/1.80	Pending Analysis	0.80/0.80	0.01/0.01	0.6/0.50	0.30/0.40	0.30/0.30	0.20/0.20	Pending Analysis
Spleen	0.50	0.10	0.20	0.20	0.30	0.10	0.10	0.90	Pending Analysis	0.40	0.01	0.20	0.30	0.10	0.20	Pending Analysis
Lumbar Marrow (Gy)	0.20	0.07	0.10	0.10	0.01	0.08	0.04	0.03	Pending Analysis	0.20	0.002	0.10	0.20	0.10	0.20	Pending Analysis

Tumor Uptake by Tumor Type
(N = 22)

Sarcoma All (Osteosarcoma)	8/11 (3/3)
Melanoma	7/8
Small Cell Lung Cancer (SCLC)	1/1
Neuroblastoma (NB)	0/2

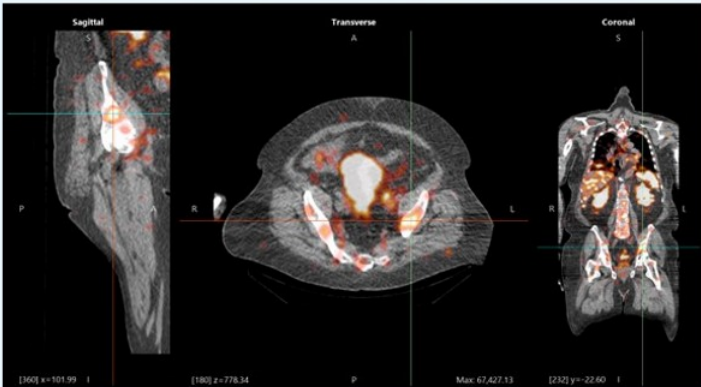
← Per protocol analysis set →

← Expanded analysis set →

Note: All data based on 30mCi ¹⁷⁷LuDOTA diagnostic dose; Gy represents absorbed dose; column colors represents cohorts
 Patient 21 (pending analysis): positive tumor uptake confirmed, dosimetry calculations on hold pending receipt of additional imaging data (CT scan)
 Patient 22 (pending analysis): organ analysis pending receipt of additional site images (planar/SPECT)

Protocol Artificially Restrained Tumor Selection and Resulted in Additional Tumors with Dose Uptake Excluded from Evaluation

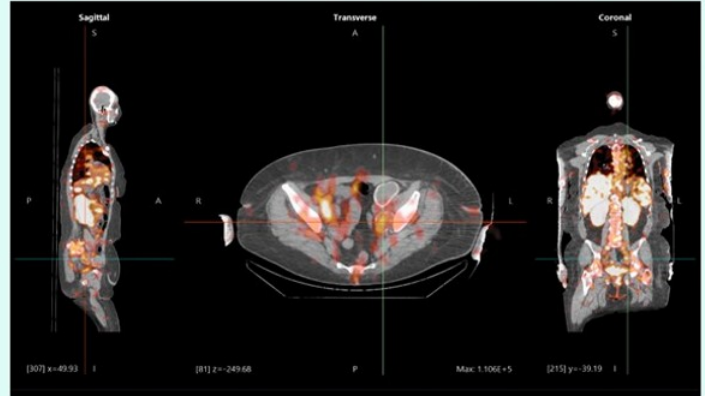
Positive Patient: Nontarget Lesion with Uptake



Patient 100-47-1001-011: Cohort 5, 1 mg/kg GD2-SADA + 3-day clearance interval, Uveal Melanoma

Patient continued onto Therapy stage as other target lesions showed uptake

Negative Patient: Nontarget Lesion with Uptake



Patient 100-48-1001-001: Cohort 4, 3 mg/kg GD2-SADA + 5-day clearance interval, Cutaneous Melanoma

Patient stopped at Imaging stage because uptake was on non-target lesions

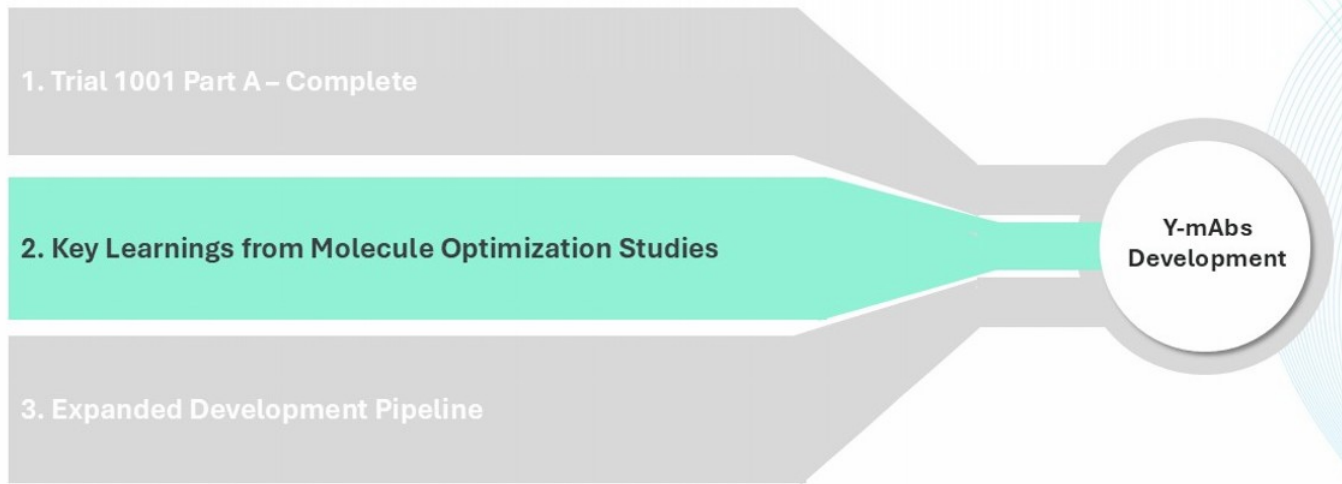
Future Trials Will Leverage Key Learning From Part A to Improve Quality of Study Data and Collection Timelines

1001 Part A – Key Learning	Implication to Platform
1 FiH demonstration of SADA shown to be safe and well tolerated with predictable PK*	Accelerate trial with parallel cohorts, single variable modifications; leverage protein PK to determine dosing interval
2 Target lesions were selected via anatomical imaging (CT) and qualitatively assessed for uptake at local site (up to 5)	Utilize central review of Nuclear Images to identify and assess all tumors
3 Imaging data provided opportunities for improved turn-around	Rapid standard-of-care dosimetry will be utilized in future trials to optimize and adapt study design
4 Dosimetry indicated we did not reach optimal therapeutic index	Optimizing GD2-SADA- ¹⁷⁷ LuDOTA is required

* Per protocol/cohorts tested



Today's Agenda: Three Key Radiopharmaceutical Updates

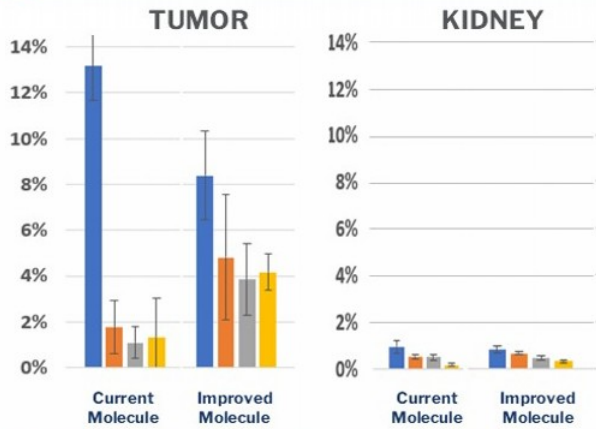


Two Studies Were Conducted in Q1 2025 to Evaluate GD2-SADA Complex and Identify Opportunities to Improve Tumor Uptake

1

Study 1:

GD2, ¹⁷⁷Lu, Neuroblastoma Model (2, 24, 48, 96 hr)

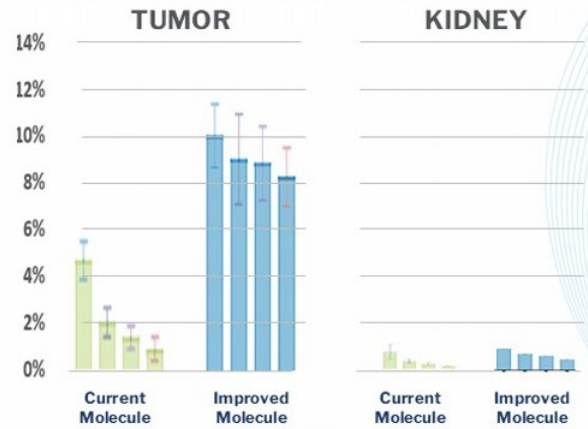


Improved Tumor Uptake
(~465% vs ~275% ID/g AUC)¹

2

Study 2:

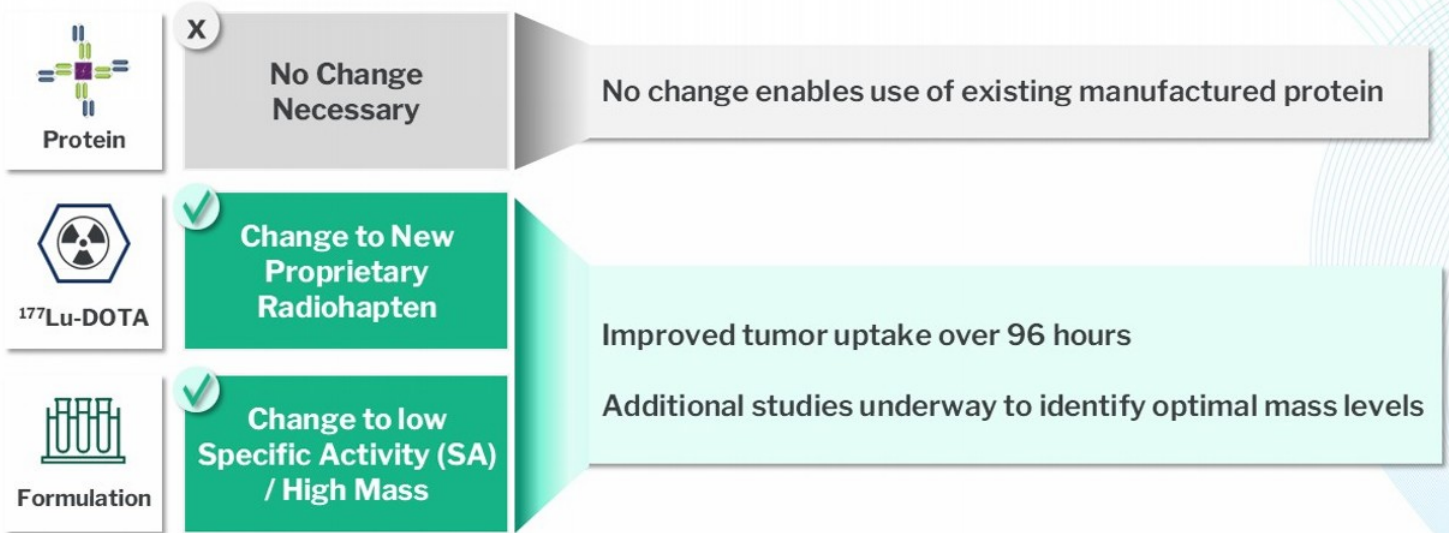
GD2, Ac225, SCLC Model (2, 24, 48, 96 hr)



Improved Tumor Uptake
(660% vs 130% ID/g AUC)²

1. MSKCC GD2-SADA Comparison, Q1'25; (Note: improved molecule includes his tag on the GD2-SADA which was deemed not meaningful to study results based on testing of other cohort permutations)
2. Minerva Imaging, GD2 SCLC Study with Ac225 Q1'25

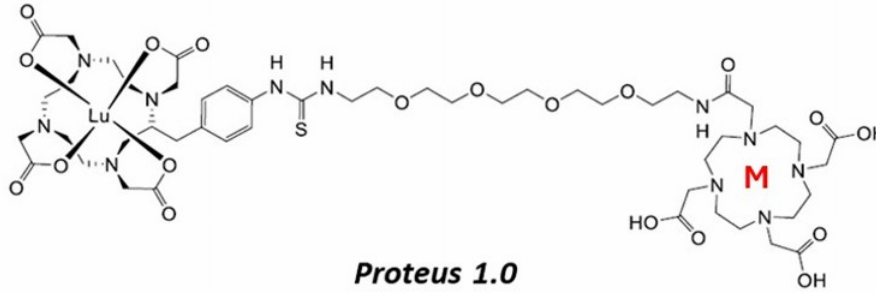
Improved Molecule Will Consist of a New Radiohaptent and Modified Specific Activity



New Radiohaptent Expands Access to a Range of Isotopes with Theranostic Applications, Including Alphas and PET

Proprietary Radiohaptent creates a “universal linker” to accommodate all payloads with picomolar affinity to anti-DOTA in SADA BsAB (with rapid clearance into the urine)

NEW - Proprietary Radiohaptent, “PROTEUS”



M=

- ^{225}Ac (alpha)
- ^{212}Pb (alpha)
- ^{177}Lu (beta) (SPECT)
- ^{90}Y (beta)
- ^{86}Y (PET)
- ^{89}Zr (PET)
- ^{111}In (SPECT)

Currently In GMP Manufacturing for Clinical Trials

The Improved Molecule Will be Incorporated into a Bridge Study in 1H 2026* Through a Proposed Amendment** to the Current IND



Trial 1001 Bridge Study (Phase 1, Part 2A)

- Confirm safety of new Radiohaptin in humans
- Assess impact of Radiohaptin and mass dose on therapeutic index
- Optimize clearance intervals (longer retention on tumor)

1H 2026 – 2H 2026*



Trial 1001 Part B ¹⁷⁷Lu Dose Escalation Trial (Phase 1/2)

- Identify MTD of Lutetium
- Explore OS, PFS, and other efficacy endpoints
- Inform patient selection with GD2-PET imaging

1H 2027 – 2H 2027*

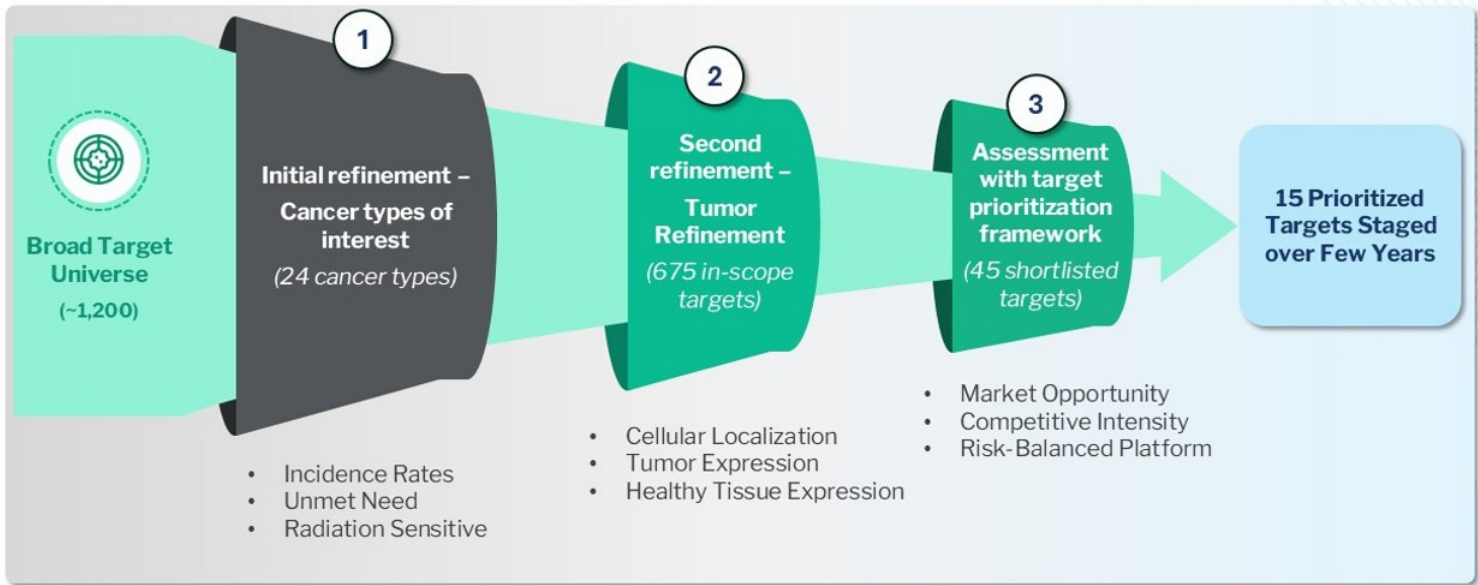
* Anticipated timing
** New IND vs. Amendment pending FDA feedback; recommendation for new IND may incur delay of 2-3 months.



Today's Agenda: Three Key Radiopharmaceutical Updates



We Conducted a Systemic Evaluation to Identify Optimal Targets for the Y-mAbs Platform and Narrowed Selection in 3 Phases



The Targets Were Phased Across 3 Years, with the Early Years Focused on Derisking the Innovative Platform

Targets are Focused on Three Franchise Opportunities		...and strategic diversification of pipeline expansion		
		2025	2026	2027
	 Lung	Good Fit, Good Validation <i>e.g. SCLC, NSCLC, TNBC, Ovarian, Gastric, Pancreatic, mCRC</i>	★	★
	 Women's Cancers	Large Market, Novel Target		★
	 Gastrointestinal	Large Market, Strong Competition	★	

Our Radiopharmaceutical Pipeline

THERAPEUTIC PIPELINE

		Asset	Isotope	R&D	Preclinical	Phase 1	Phase 2
GD2	R/R SCLC, Sarcoma, Malignant Melanoma, HR Neuroblastoma	GD2-SADA-¹⁷⁷Lu-Proteus	¹⁷⁷ Lu				
CD38	R/R Non-Hodgkin Lymphoma	CD38-SADA	¹⁷⁷ Lu				
Undisclosed	Colorectal Cancer	Antibody	Ac225				
Undisclosed	Lung, TNBC, Ovarian, Gastro	Antibody	Alpha/Beta				
Undisclosed	Solid Tumors	Antibody	Alpha/Beta				

MOLECULAR IMAGING PIPELINE

		Asset	Isotope	R&D	Preclinical	Phase 1	Phase 2
GD2	R/R SCLC, Sarcoma, Malignant Melanoma, HR NB, Osteosarcoma	⁸⁹Zr-DFO-naxitamab	⁸⁹ Zr				
Undisclosed	Colorectal Cancer	Undisclosed	⁸⁹Zr (⁶⁴Cu)				
Undisclosed	Lung, TNBC, Ovarian, Gastro	Undisclosed	Undisclosed				
Undisclosed	Solid Tumors	Undisclosed	Undisclosed				

Radiopharmaceuticals: Multiple Potential High Value Inflection Points Anticipated Ahead

Increasing commitment, capabilities, and leadership in Radiopharmaceuticals

2024	2025	2026	2027
<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Increased organizational focus on Radiopharmaceuticals <input checked="" type="checkbox"/> New Executive Team appointed with deep Radiopharma expertise 	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Realignment into two business units: DANYELZA and Radiopharmaceuticals <input checked="" type="checkbox"/> CD38-SADA FPI in 1H 2025 <input checked="" type="checkbox"/> GD2-SADA Trial 1001 Part A Data Readout <input type="checkbox"/> GD2-Diagnostic IND Submission in 2H 2025 	<ul style="list-style-type: none"> <input type="checkbox"/> GD2-Diagnostic FPI 1H 2026 <input type="checkbox"/> GD2-SADA 1001 IND Amendment* 1H 2026 <input type="checkbox"/> Initiate GD2-SADA Bridge Study with new Radiohaptens in 1H 2026 <input type="checkbox"/> Trial 1001 Bridge Study Data Readout with new Radiohaptens in 2H 2026 	<ul style="list-style-type: none"> <input type="checkbox"/> Initiate Dose Escalation Study (Trial 1001, Part B) in 1H 2027 <input type="checkbox"/> Initiation of GD2-SADA Pediatric Study (Trial 1002) in 1H 2027 <input type="checkbox"/> GD2-SADA Pediatric Trial (Trial 1002) Data Readout in 2H 2027 <input type="checkbox"/> GD2-SADA Dose Escalation Study (Trial 1001, Part B) Data Readout in 2H 2027 <input type="checkbox"/> NEW TARGET: IND submission (mCRC) in 1H 2027 <input type="checkbox"/> NEW TARGET: FPI New Therapeutic (mCRC) 2H 2027

* New IND vs Amendment pending FDA feedback; recommendation for new IND may incur delay of 2-3 months

In Conclusion: Recent Insights Will Be Scaled Across the Platform

- ★ **GD2-SADA Protein is safe and well-tolerated**
- ★ **Protein PK and dosing interval optimize the Therapeutic Index**
- ★ **New Universal Radiohaptens expected to modularize the platform, allow for multiple isotopes, and improve tumor retention**
- ★ **New targets expand value opportunity by addressing large unmet medical needs**
- ★ **Safe platform, predictable PK and improved operations will accelerate development**

Q&A

Thank You



**Y-mAbs Hosts Virtual Radiopharmaceutical R&D Update
Highlighting Clinical Progress and Expanded Pipeline**

- *Company's Part A data readout from first-in-human Phase 1 Trial 1001 in patients with recurrent or refractory metastatic solid tumors known to express GD2, validates GD2-SADA as safe, tolerable and able to achieve targeted in vivo conjugation of ¹⁷⁷Lu-DOTA*
 - *Increased tumor retention and total tumor uptake anticipated by using optimized universal Radiohaptan*
- *Company plans to initiate a Trial 1001 Bridge study (Part 2A) with optimized Radiohaptan, "Proteus", in 1H 2026 with data readout in 2H 2026; Part B of Trial 1001 anticipated to initiate with Proteus in 1H 2027 with data readout in 2H 2027*
- *Expanded Radiopharmaceutical pipeline to focus on target franchise areas in oncology, with specific programs that maximize pretargeting approach in high-value commercial targets*
- *Company to host virtual Radiopharmaceutical R&D update today at 8:00 a.m. ET*

Princeton, NJ, May 28, 2025 – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel radiopharmaceuticals, and commercial stage antibody-based therapeutic products for the treatment of cancer, today announced that the Company plans to highlight progress across its Radiopharmaceutical Business Unit during a virtual R&D update to be held today, Wednesday, May 28, 2025 at 8:00 a.m. ET.

"At Y-mAbs, our mission is to deliver innovative therapeutic solutions for life-threatening diseases and improve the lives of patients and their families," said Michael Rossi, President and Chief Executive Officer. "We are excited to provide these updates across our Radiopharmaceutical Business today, share data confirming our pretargeted approach has been validated in humans, and reiterate the potential of our platform to deliver novel products that we believe will have a meaningful impact on how we treat certain cancers. Based on today's update, we reaffirm our commitment to accelerating the clinical advancement of our Self-Assembly DisAssembly Pretargeted radioimmunotherapy ("SADA PRIT") technology platform and pipeline."

"The complete Part A data from Trial 1001 highlighted today provides further validation for our novel SADA PRIT technology platform," said Natalie Tucker, Radiopharmaceutical Business Unit Head. "This data from Part A of Trial 1001 adds to the substantial learning we have developed through clinical and preclinical research regarding our SADA PRIT technology. Based on our work, we believe that SADA is a truly differentiated pretargeted platform positioned to potentially disrupt the radiopharmaceutical industry and significantly improve patient outcomes."

Radiopharmaceutical R&D Update Highlights

GD2-SADA Phase 1 Clinical Trial (Trial 1001): Part A Completed

- The primary objective of Trial 1001 is to evaluate the safety and tolerability of GD2-SADA in adult and adolescent patients with recurrent or refractory metastatic solid tumors, including small cell lung cancer, sarcomas, malignant melanomas, and high-risk neuroblastoma. In Part A, the Company first explored variable protein doses of 0.3, 1.0, and 3.0 mg/kg and a pre-targeting interval of two to five days.
- Of the 22 patients dosed with both the GD2-SADA Protein and ¹⁷⁷Lu-DOTA, nine patients had positive GD2 expression, per protocol, and were eligible for the therapeutic stage of the study to receive up to 200 mCi of ¹⁷⁷Lu-DOTA.

- The initial concentration of administered GD2-SADA Protein correlated with the amount of GD2-SADA in serum at the Cmax and over time (AUC).
- The GD2-SADA Protein PK was highly reproducible within cohorts, and when normalized by dose concentration similar Cmax and clearance rates were observed over time.
- These results demonstrate that the GD2-SADA Protein clearance rate is reliably correlated to dose concentrations and PK provides a roadmap for tailoring the clearance interval prior to isotope administration.
- Higher concentrations of ¹⁷⁷Lu-DOTA were correlated with higher GD2-SADA Protein concentrations, indicating effective targeting of the ¹⁷⁷Lu-DOTA to GD2-SADA.
- Part A of Trial 1001 demonstrated positive tumor uptake and quantifiable absorbed dose to the tumor at 30 mCi.
- Both the GD2-SADA and ¹⁷⁷Lu-DOTA administrations were generally safe and well-tolerated. No treatment-related serious adverse events occurred across all dosing cohorts and there were no reports of serious treatment-related pain that has been historically associated with dosing of anti-GD2 therapies.

SADA Optimization Data

- The Company completed a number of pre-clinical studies over the last few quarters to evaluate multiple GD2-SADA-¹⁷⁷Lu-DOTA molecule constructs for optimizing tumor-to-organ ratios. Results from this extensive work have demonstrated that the ¹⁷⁷Lu-DOTA and molecule formulation can be optimized to improve tumor uptake and retention. Accordingly, the Company has chosen to move forward with “Proteus,” a novel universal radiohaptent which has demonstrated the potential to expand access to a range of isotopes with theranostic applications.
- Y-mAbs is committed to advancing its GD2-SADA program and achieving accelerated validation of Proteus to leverage across its platform and new target programs. The Company plans to file an amendment to its current IND for Trial 1001 to incorporate Proteus for a Bridge study (Part 2A) as part of Trial 1001. The Bridge study aims to assess the safety of Proteus in patients and the impact of mass dose on the therapeutic index. The Company anticipates initiating the Bridge study in the first half of 2026.
- Following completion of the Bridge study, Y-mAbs anticipates launching the dose escalation portion of Trial 1001, Part B, which is expected to be a Phase 1/2 clinical trial, in the first half of 2027 with data in the second half of 2027.

Expanded Radiopharmaceutical Development Pipeline

- Following a systematic evaluation to identify optimal targets for its novel SADA platform, Y-mAbs has selected lung cancer, women’s cancers, and gastrointestinal cancers as target oncology franchise-expanding opportunities. In addition, the Company has established a discovery and pre-IND molecular imaging portfolio, complementary to its planned therapeutic portfolio. The Company anticipates filing an IND for its first molecular imaging asset by the end of 2025.

Webcast Information

The duration of the virtual Radiopharmaceutical R&D update is expected to be 90 minutes. A live audio webcast of the call will be available on the Investor Relations section of the Company’s website at <https://ir.ymabs.com/events-and-presentations/events>. The webcast will be archived for at least 30 days.

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.

About GD2-SADA PRIT

GD2-SADA is a bispecific fusion protein that tightly binds to the glycolipid GD2 and Lutetium 177 (Lu ¹⁷⁷)-DOTA, a chelated or "caged" radionuclide. In the first step of pre-targeted radiotherapy, non-radiolabeled GD2-SADA tetramers are infused and bind to GD2-expressing solid tumors, while unbound GD2-SADA protein disassembles into low molecular weight monomers that are removed by the kidney. The second infusion delivers the "radioactive payload," which binds directly to GD2-SADA on tumor cells for localized irradiation. GD2-SADA PRIT with ¹⁷⁷Lutetium-DOTA has demonstrated anti-tumor activity in preclinical studies and is currently being investigated in adults and adolescents with GD2-expressing solid tumors in Trial 1001 (NCT05130255).

Researchers at Memorial Sloan Kettering Cancer Center (MSK), including Dr. Nai-Kong 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.

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 Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about the clinical development of the Company's Radiopharmaceutical product candidates, including the progress of and results from ongoing clinical trials and the timing of initiation of additional clinical trials; the potential of the Company's SADA technology to disrupt the radiopharmaceutical industry and significantly improve patient outcomes; and the timing of regulatory filings for the Company's product candidates and expectations regarding the expansion of its oncology franchise. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," "guidance," "goal," "objective," 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 the Company's financial condition and need for additional capital; the risks that actual results of the Company's recent business realignment will not be as expected; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials including if we encounter difficulties enrolling patients in our clinical trials; the risks of delay in the timing of the Company's or its partners' regulatory submissions or failure to receive approval of its drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of product candidates; development of sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for products; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture as well as regulatory submissions; the Company's ability to enter into new partnerships or to recognize the anticipated benefits from its existing partnerships; risks related to government regulation; risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks associated with macroeconomic conditions, including the conflict between Russia and Ukraine and Israel and Hamas and sanctions related thereto, international trade policies, including tariffs and trade restrictions, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, and future filings and reports by the Company. 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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