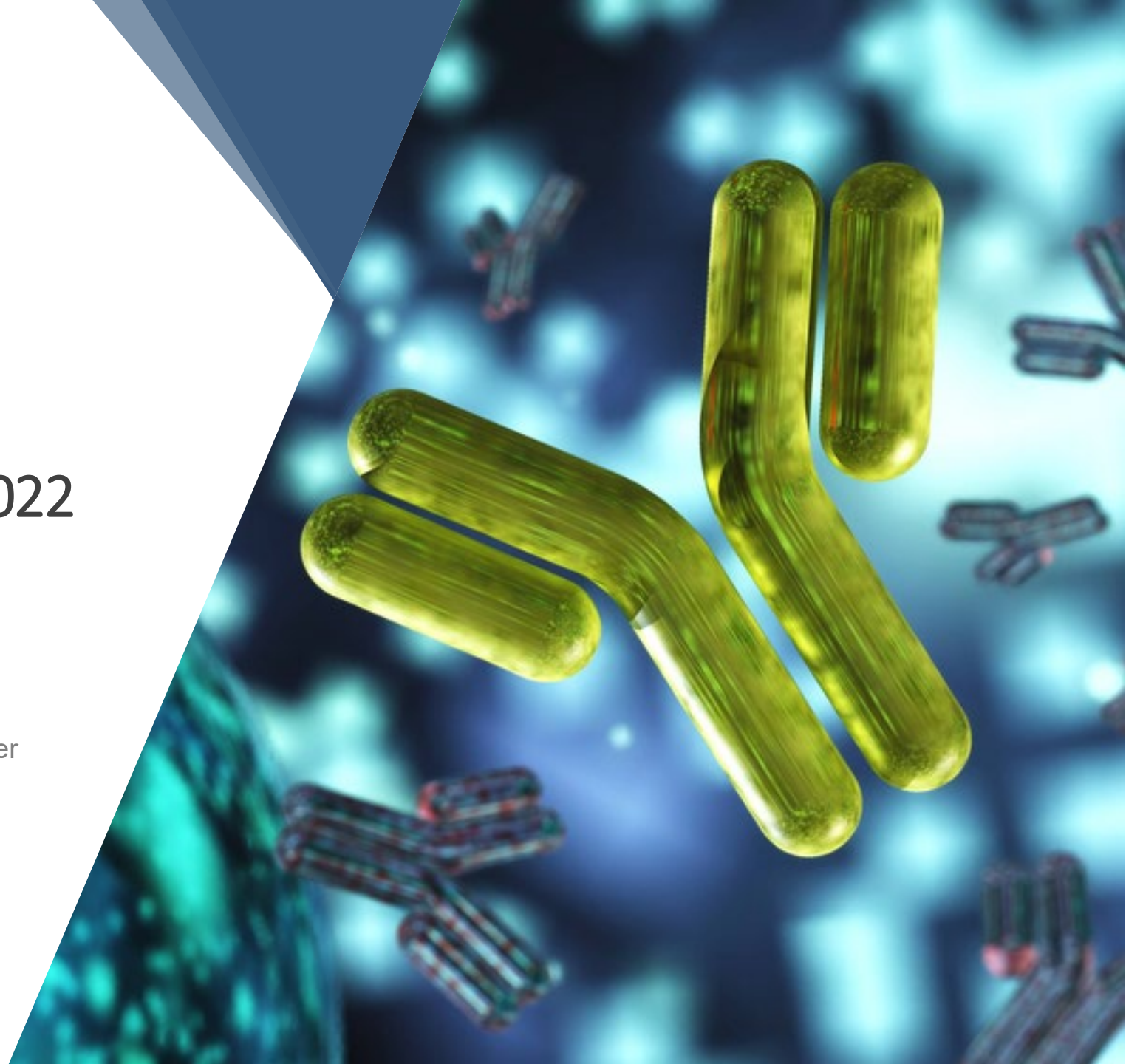
mAbs Therapeutics, Inc.

R&D Day December 14th, 2022

Welcome by Thomas Gad

Founder, President, and Interim Chief Executive Officer



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This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties or us. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. All of the market data used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The industry in which we operate is subject to a high degree of uncertainty, change and risk due to a variety of factors, which could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the compound and Y-mAbs.

Omburtamab next steps

- 30-Nov-2022: Complete Response Letter (CRL) received
- 16-Dec-2022: Submitting request for Type A meeting
- 16-20 Jan 2023: Type A meeting with the purpose to discuss appropriate steps to remediate clinical and statistical deficiencies and to reach agreement on the following:
  - Discuss possible designs for an adequate and well-controlled trial with supportive evidence, which may support a resubmission of BLA 761176.
  - Discuss feasible methodology to demonstrate antitumor activity for ^{131}Iomburtamab for the intended indication via the proposed route of administration.

We remain dedicated to patients with pediatric cancers

Continued **DANYELZA** franchise with investigational studies in 1st line Neuroblastoma, 2nd line Osteosarcoma and other adults indications

Continued Ex-US Sales growth through external partnerships (SciClone, Takeda, Adium)

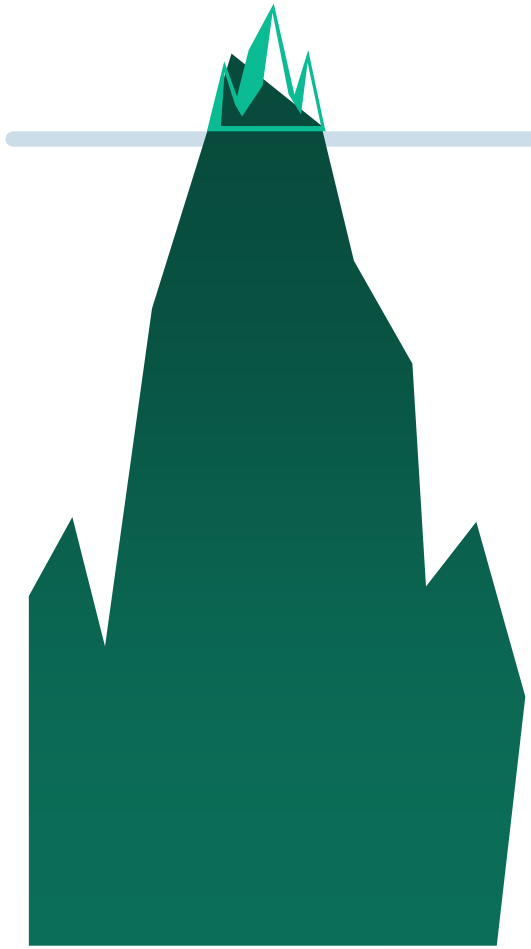
Advancement of investigational **SADA** technology platform with the goal to become the go-to partner for large market indications

Strong financial resources to drive near and long-term growth

- $115 M cash on hand - Omburtamab revenues and PRV were never part of company guidance
- Conservative financial planning to preserve resources extending cash runway into 2025

Commercial Opportunities – DANYELZA®

Current, potentially expanded label and new indications



Addressable US patient population

Neuroblastoma – HR-NB	350	2nd Line
Neuroblastoma	450	Front line
Osteosarcoma/ Recurrent	200	2nd Line
NB Ex US Sales; China,LATAM, Israel	700+	2nd Line
Soft-Tissue Sarcomas	2,900	1st Line
Triple Negative Breast Cancer	8,900	2nd Line 3rd Line *Plus*
Melanoma (newly unresectable and metastatic)	11,400	2nd Line 3rd Line *Plus*

[1] Assumes 80% of newly unresectable or metastatic patients are treated

Cancers	GD2 expression	
Neuroblastoma[1,2]	~99-100%	**FDA approval for HR-NB in Nov 2020**
Osteosarcoma[3,4]	~88%	**Investigational** For further clinical development – safety/efficacy have not been established by health authorities and not approved.
Soft-tissue Sarcomas[5]	>90%	
Triple Negative Breast cancer[6]	>50%	
Melanoma[7]	>50%	

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 is 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 benefit in a confirmatory trial(s).

Source for sarcoma, breast cancer and melanoma: Clarivate, 2021
1. Wu Z. Et al. Cancer Res. 1986; 46: 440–443.
2. Modak, S. Et al. Cancer Invest, 25: 67-77.
3. Heiner JP, et al. Cancer research 1987;47(20):5377-81
4. Roth M, et al. Cancer 2014;120(4):548-54 doi 10.1002/cncr.28461.
5. Helena R. Chang, et al. Cancer, Aug 2, 2992, Vol 70, No.3
6. Ly S, et al. *J Immunother Cancer.* 2021;9(3).
7. Hersey P, et al. International Journal of Cancer 41:336-343, 1988

Danyelza: 28% ↑ q/q in Q3 → Driving for Continued Growth Next Year

- Heavily focused on Priority & Key accounts and here we have identified 63 that represent 75% of the overall GD2 market. We have achieved 26 leaving us 37 sites within this core segment to grow
- Depth of Experience; Growth coming from the number of sites treating two or more patients outside of MSK, currently 25% of our prescribers have treated 2+ patients
- 7 out of 11 new Patient Starts coming from Large Academic Centers
- 21% of our patients have received 5+ cycles and 7% have received 8+ cycles leaving meaningful growth
- Danyelza is now 12% of the anti-GD2 market, our highest since launch
- Launch in China targeting 40+ hospitals along with a strong KOL engagement plan with dedicated 15-person team

Self-Assembly – DisAssembly SADA 2-Step Pre-targeted Platform

- In vivo non-clinical data support that we can target tumors with high payload exposures w/out exceeding acceptable normal tissue exposure
- In ongoing animal toxicity study models, no dose restrictions as compared to expected human dose exposures has been revealed
- Research has shown that GD-SADA Tetramer construct was far superior as compared to a monomeric state construct in terms of tumor uptake, avidity, time on target and anti-tumor responses seen in tumor bearing mice
- Potential early de-risking of SADA programs collecting pharmacokinetics data by imaging using radioactive isotope imaging doses directed at the same cancer target as the therapeutic agent showing the therapeutic drug absorbed prior to administering a high payload to the tumor
- First site, City of Hope is open and actively pre-screening patients
- Total of 6 sites expected to be open in Q1 2023
- Validation leading to partnerships focusing on our in-house targets and optimization targets from third parties

SADA is investigational - Safety/efficacy have not been established by health authorities and not approved.

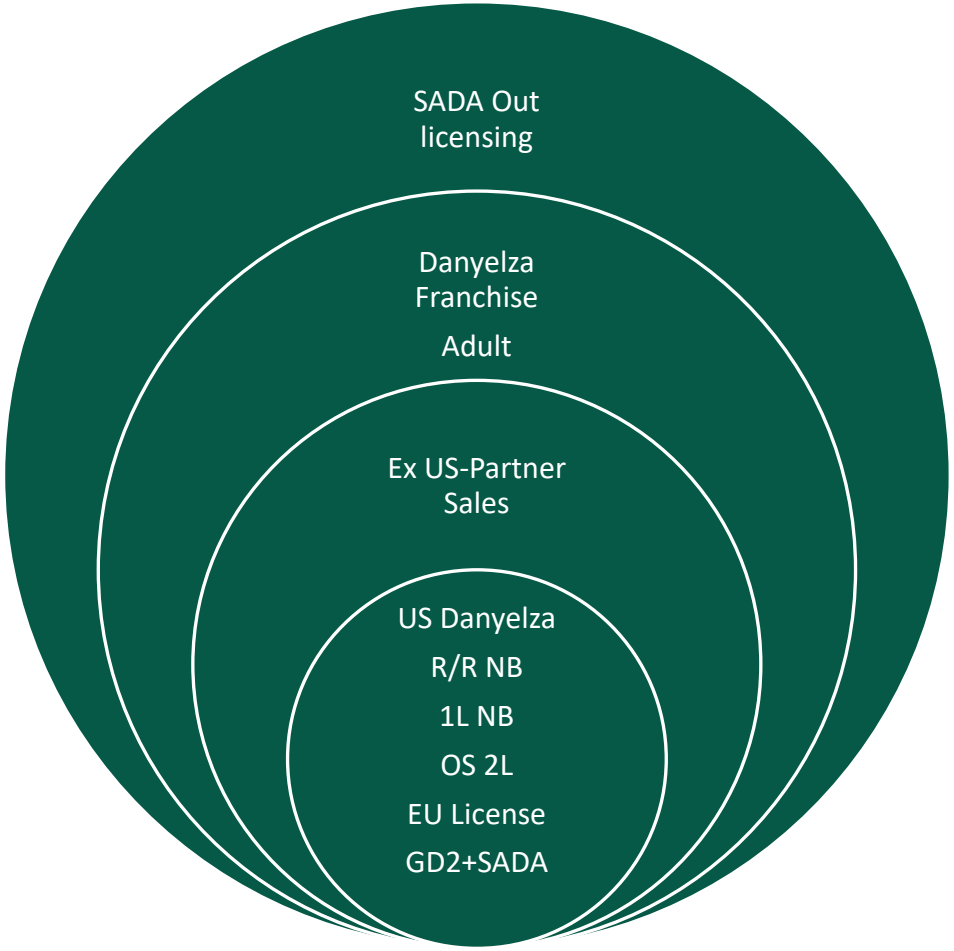
Y-mAbs: Refining Focus, Driving Organic Growth

- Cash on hand of ~$115 million at Sept 30, 2022
- Danyelza Approval in China - Dec 8th, 2022, triggers $15M milestone payment
- Conservative financial planning continues to provide ample options to preserve resources

- Two key platforms represent near-term and *transformational* upside
  - GD2 – DANYELZA is a pipeline within a product with potential extension into:
    - 1st line R/R Neuroblastoma – 450 patients per year
    - 2nd line Osteosarcoma – 200 patients per year
    - Adult indications (via partnerships) – significantly larger opportunities
  - SADA – Goal: become the go-to partner for large markets; keep pediatric ones
    - YMAB (Nutley) team overcame industry CMC challenges; creating broad opportunity
  - **SADA partnership revenues and royalties represent largest potential value-driver for YMABS**

Y-mAbs Focus 2023-2025

Size of Circle represents income potential



Y-mAbs Corporate Revenue drivers
#1 SADA
#2 Danyelza


THANK YOU

Development and Progress on Investigational SADA platform; December 14th , 2022

Steen Lisby, MD, DMSc

SVP, CSO,

Global Head Translational Medicine

SADA programs are investigational. Safety/efficacy have not been established by health authorities.

SADA: Self-assembling and disassembling bispecific antibodies

Aim

- To develop a 2-STEP pre-targeting Radio ImmunoTherapy Platform.
- To develop a technology to be used for more targets as well as payloads

Differentiation

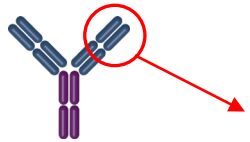
- Due to molecule structure, disassembly properties potentially allows for PK optimization for subsequent payload administration
- Non-clinical research has shown that most of SADA protein already cleared from circulation when administration of radioactive payload

Benefit/Risk

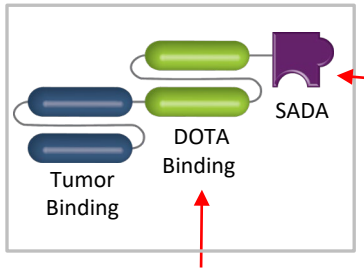
- In non-clinical studies, low uptake in normal tissues / BM and blood observed
- The 2-step approach potentially would allow the protein administration to be separated from handling the radioactive payload.

SADA: The Molecule and Principle

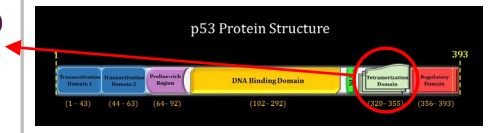
Design: protein consisting of two single-chain variable fragments (scFv) + tetramerizing peptide (SADA)



Tumor-specific IgG monoclonal antibody: scFv domains from heavy and light chains



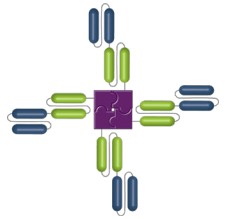
DOTA specific IgG monoclonal antibody: scFv domains from heavy and light chains

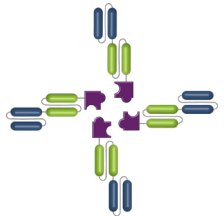


SADA domain derived from human TP53 protein: only tetramerization peptide

Self-assembled:

- 240 kDa tetramer (~1-2 IgG antibodies)
- Slower clearance
- Higher tumor binding (4 arms)





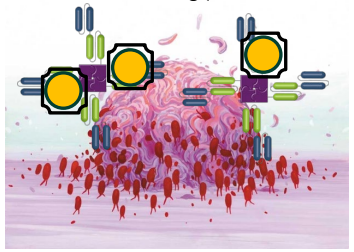
DisAssembled:

- 60 kDa monomer (~1 BiTE)
- Rapid clearance

DOTA (chelator) is used as a complexing agent. Its complexes can have medical applications both as contrast agents and cancer treatments. DOTA can be labelled with e.g. ^{177}Lu (Therapy), ^{90}Y (Therapy) or ^{86}Y (Imaging).

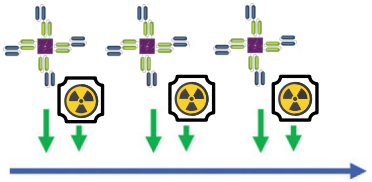
In vitro characterization:

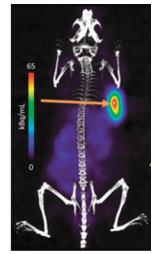
- Affinity (SPR)
- Cell binding (Flow Cytometry)
- DOTA binding (ELISA, SPR with non-radioactive DOTA)



In vivo characterization:

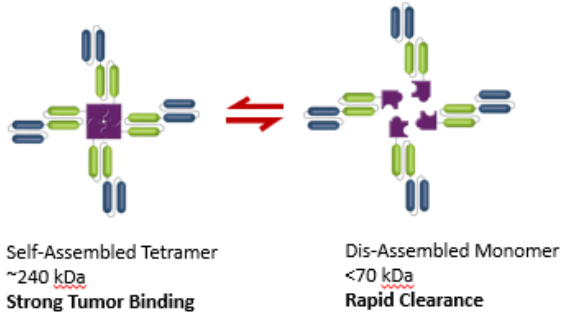
- Tumor uptake/dosimetry (PET or SPECT/CT imaging)
- Serum Pharmacokinetics (ELISA)
- Tumor responses





1: Anti-DOTA domain: Orcutt et al 2011, 10.1016/j.nucmedbio.2010.08.013

SADA; 2-step pre-targeted RIT



SADA represent a 2-step **S**elf-**A**ssembly and **D**is**A**ssembly-Bispecific DOTA-Engaging antibody system – concept referred to as Liquid Radiation™

Step 1:

Tumor pre-targeting; SADA molecule (**cold**) is administered and binds to target (e.g., tumor). The molecule is PK optimized for rapid clearance (as compared to IgG).

In non-clinical assays, within 24-48 hours, non-bound SADA disassemble and is cleared from circulation.

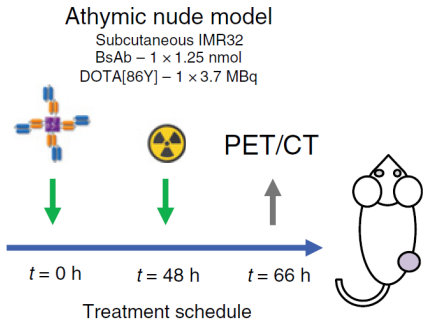
Step 2:

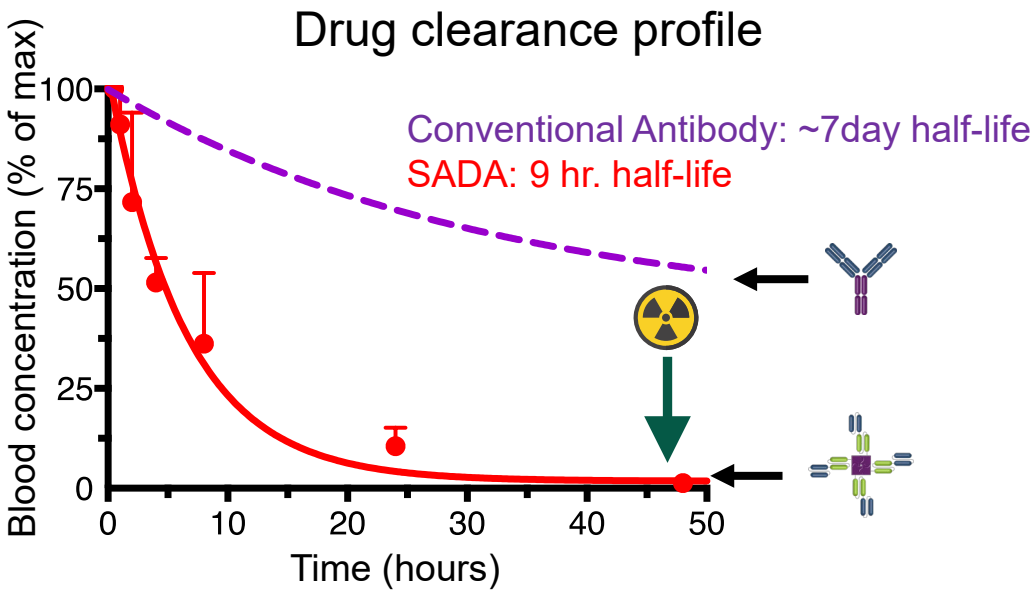
Administration of payload; Payload is administered. Initial payload; ^{177}Lu complexed to DOTA "^{177}Lu- DOTA".

The ^{177}Lu-DOTA can bind to the "anti-DOTA" segment of the SADA molecule. Unbound payload (^{177}Lu-DOTA), based on non-clinical data is expected to be cleared from circulation within hours.

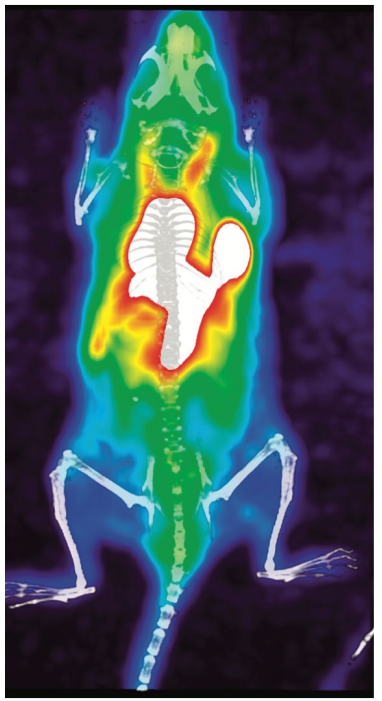
SADA Platform demonstrates a unique clearance profile in non-clinical experiments

Results from experiments in mice suggest strong binding to target (GD2) and fast elimination compared to conventional IgG-based antibody

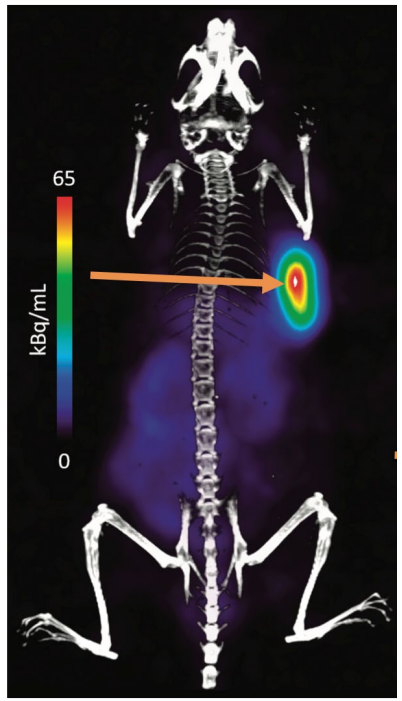




2-step IgG PET



2-step SADA PET

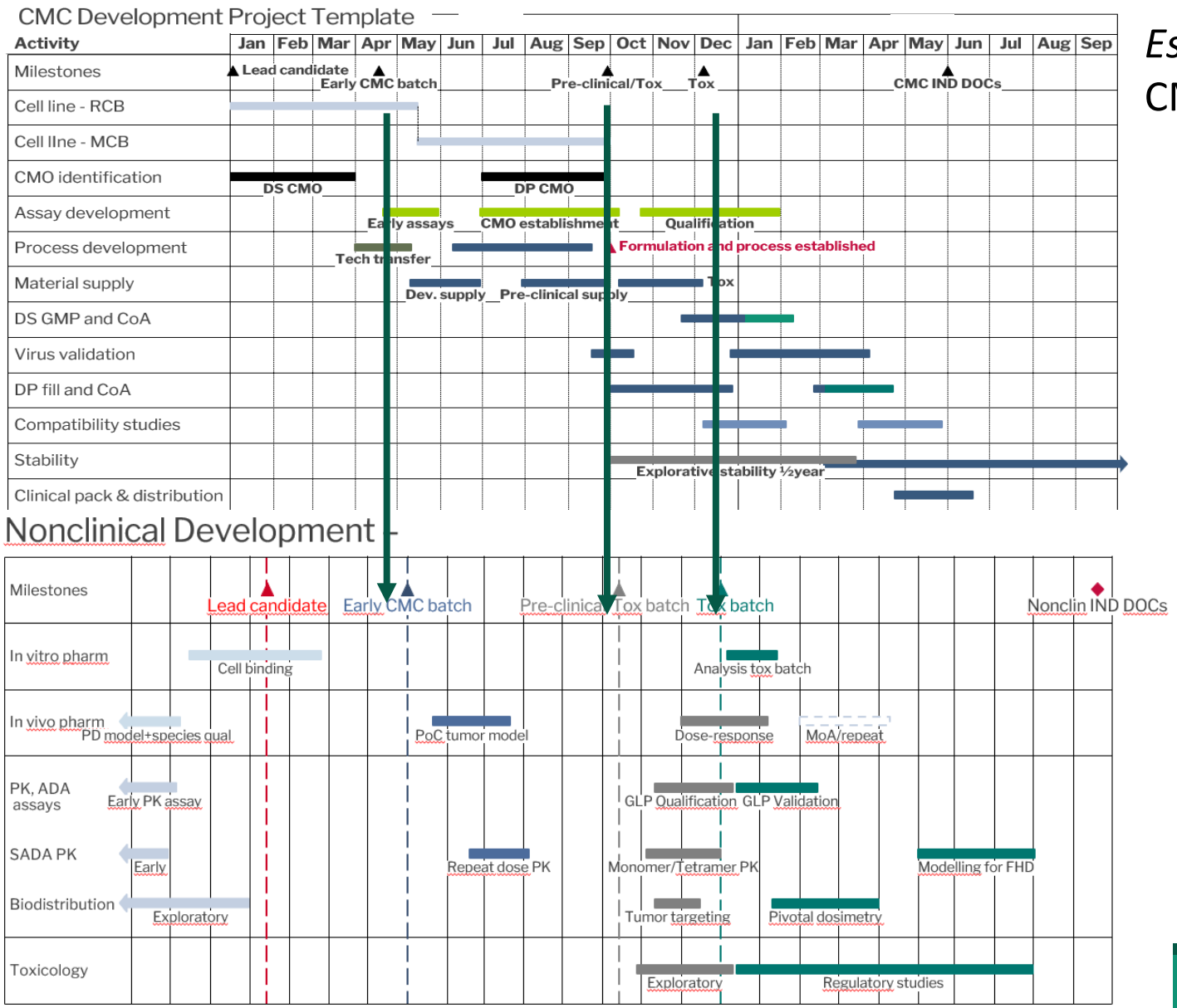


24h after
BnDOTA 86Y

Adapted from Santich *et al.*, Clin Canc Res 2020

Y-mAbs' project CMC and non-clinical timelines post Lead Candidate Selection

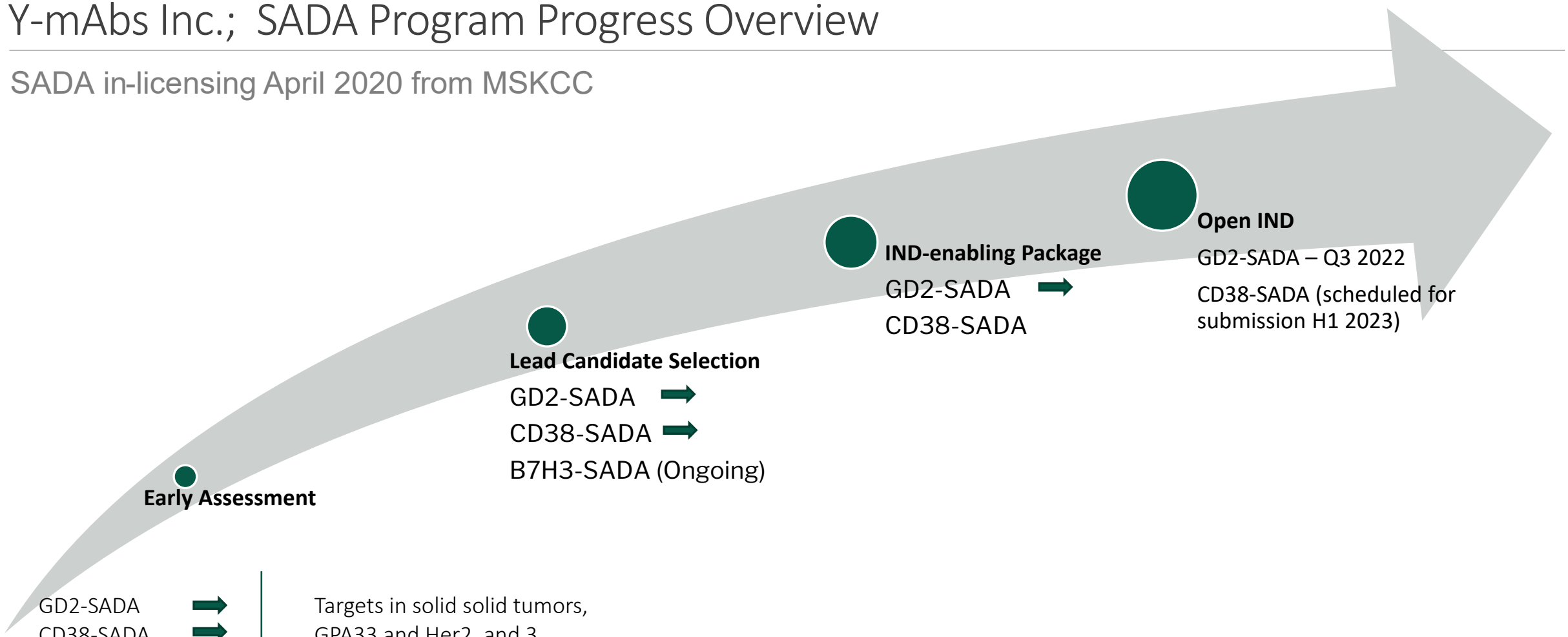
- seek to balance speed and level of analyses



Estimated Generic timelines for CMC + nonclinical Development

Y-mAbs Inc.; SADA Program Progress Overview

SADA in-licensing April 2020 from MSKCC



-mAbs Therapeutics, Inc.

GD2 SADA

1st SADA program

First study open for enrolment

GD2; The Target

Antigen

- Disialoganglioside (carbohydrate-containing sphingolipid) and belongs to a class of T-cell independent carbohydrate antigens.
- Valid target - FDA has approved two monoclonal antibodies directed towards GD2 (dinutuximab and naxitamab).

Expression

- Limited normal tissue expression. GD2 is expressed on e.g. peripheral neurons and pain fibers.
- Highly expressed in a variety of tumors incl neuroblastoma, osteosarcomas, melanoma, and SCLC

Development

- Initial development within relapsed/ refractory setting.

GD2 SADA - Status

CMC

- Successfully designed and effectuated CMC campaign within 2-year period
- Fully FDA approved CMC IND package

Non-Clinic

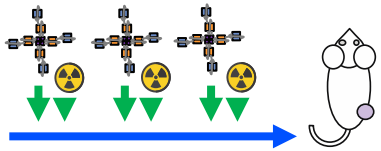
- Successfully designed and effectuated Non-Clinical campaign within 2-year period
- Fully FDA approved non-clinical IND package

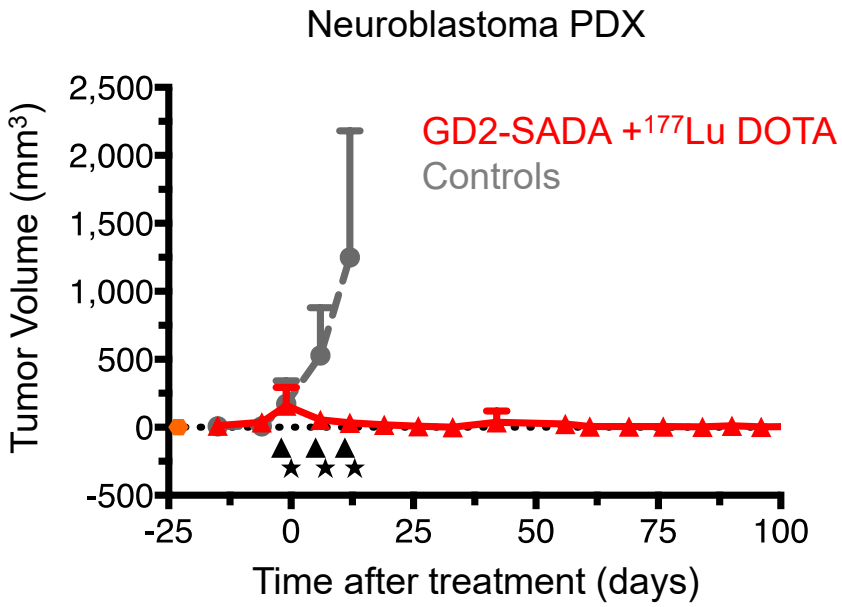
Clinic

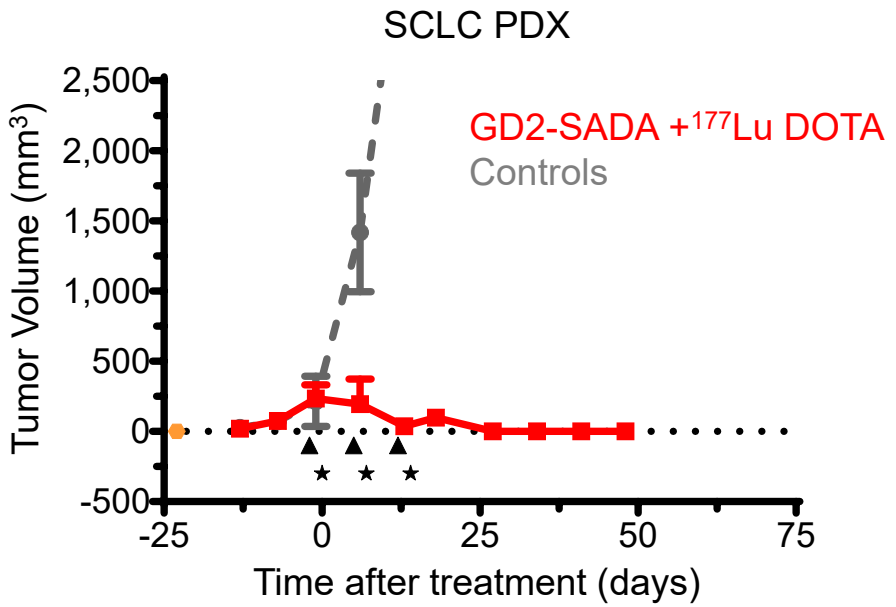
- IND open, and an FDA approved clinical phase I protocol in adult patients
- First site open for enrolment – Trial is listed on ClinicalTrials.gov

GD2-SADA in established tumors in mouse models using ^{177}Lu

PDX models; Neuroblastoma and Small cell lung cancer (SCLC)







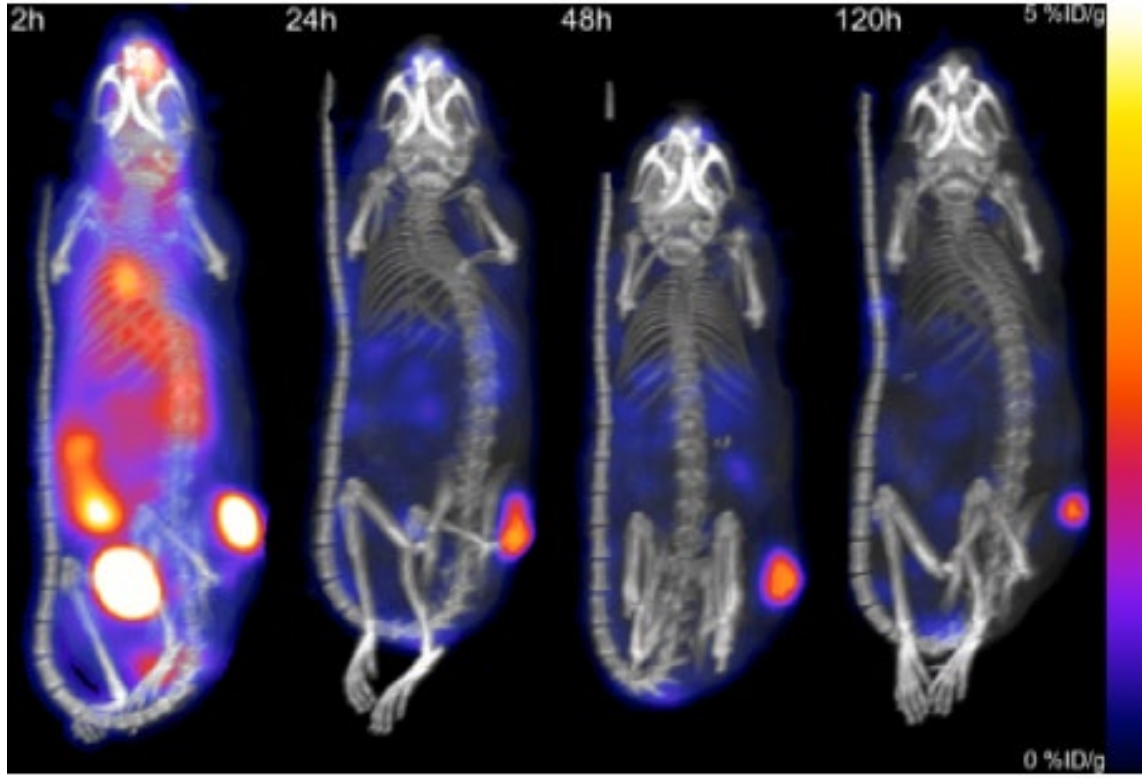
Model: BRG mice with s.c. PDX
Doses: 1x weekly for 3 weeks with 48hr interval,

Model: BRG mice with s.c. PDX
Doses: 1x weekly for 3 weeks with 48hr interval

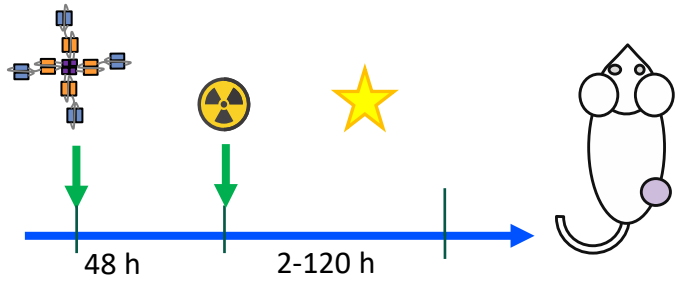
Adapted from Santich et al. Clin Canc Res 2020 and unpublished data

GD2-SADA binds tumors and ^{177}Lu-DOTA in vivo: IMR-32

Tumor uptake measurements by SPECT/CT



Nude mice with s.c. xenografts (IMR-32)



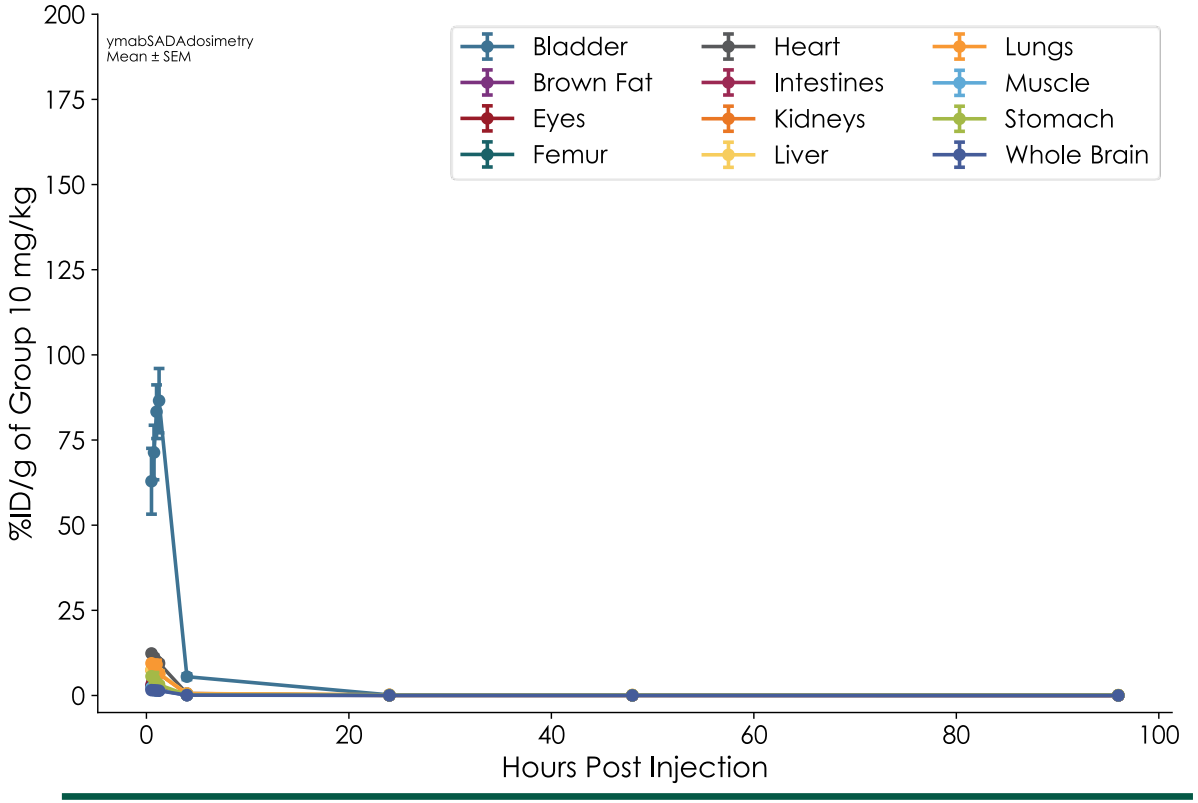
0 hr: GD2-SADA
48 hr: ^{177}Lu-DOTA
2-120 hr: SPECT/CT

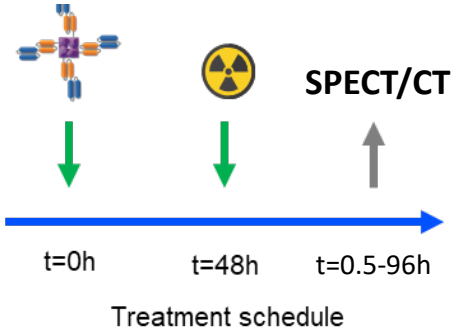
IMR-32: Study # YMAB-2021-CR01

Non-clinical Biodistribution study confirms clearance from normal tissues (mouse)

GD2-SADA administered to normal Balb/C mice. ^{177}Lu-DOTA 48 hrs later.

SPECT/CT: 1hr dynamic read 0.5-1.5hr post DOTA, 30min scans at 4, 24, 48, 96-hour timepoints.



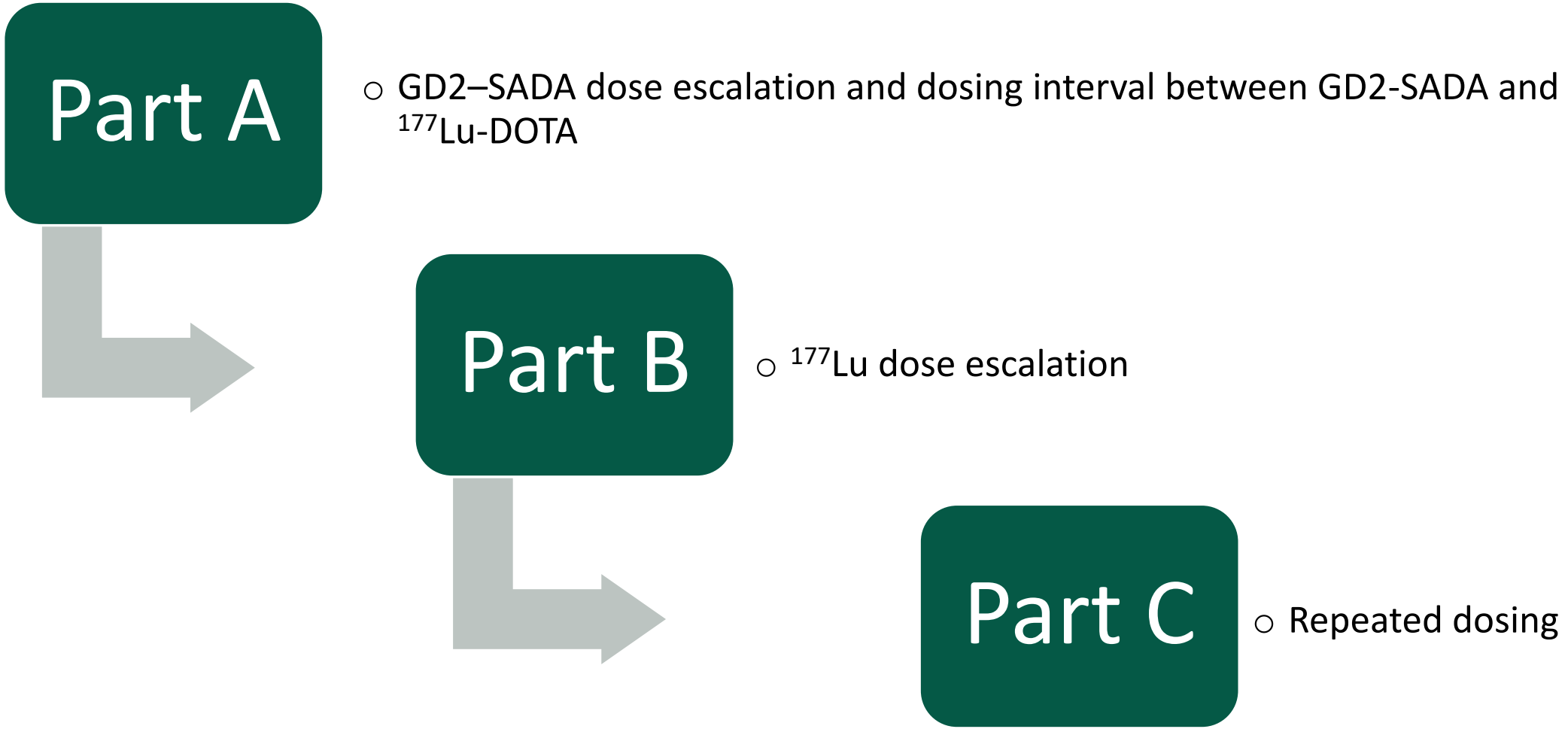


Organ	Organ limit (Gy)	Estimated Max dose in humans NOT exceeding 5% of organ limits
		mCi
Red Marrow	2	✓
Kidney	18	✓
Liver	30	✓

OLINDA/EXM 2.0 used for human absorbed dose estimation.

Unpublished internal data

GD2 SADA; FiH, Phase 1 Clinical Trial Protocol : 1001



GD2 SADA; Clinical Development Plan

Clinical FiH Trial 1001

- Clinical approach involved FiH development in adult patients (as per FDA recommendations)
- Theranostic approach involving imaging dose followed by full therapeutic dose in patients with tumor uptake
- To test a) SADA protein concentration, b) spacing, c) ^{177}Lu DOTA dose and d) repeat dose safety and efficacy
- Indications include SCLC, Sarcomas and malignant melanoma

CDP

- Based on FiH – line expansions / separate clinical phase II (II/III) study initiation

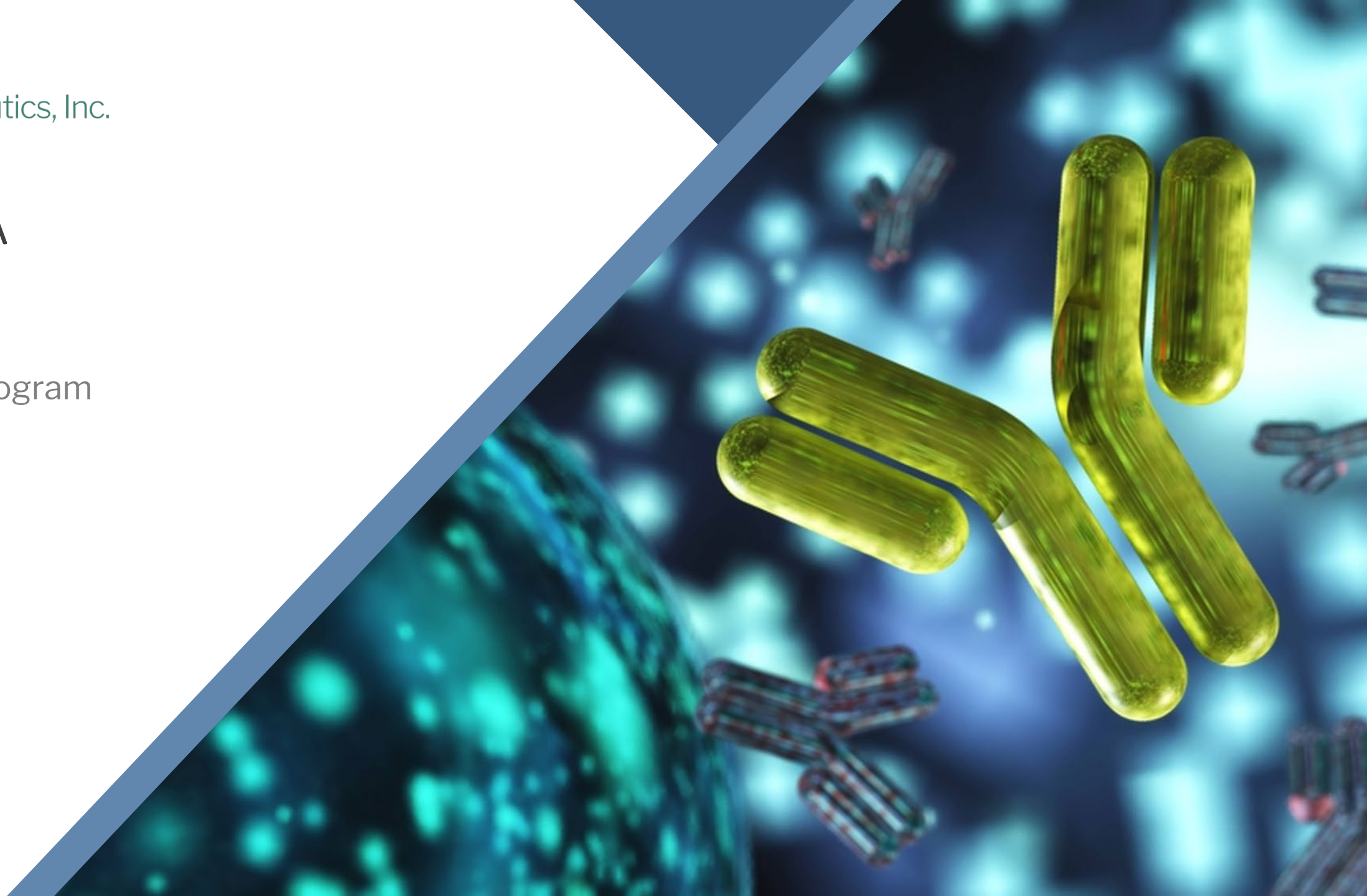
Trial 1001 sites

- 6-8 clinical sites planned opened (sequentially)
- Study lead Site: Dr. Taofeek Owonikoko, Chief of the Division of Hematology/Oncology, UPMC (PA)
  - MSKCC (NYC); Honor Health, Arizona (AZ); City of Hope (CA); University of Wisconsin (WI)

-mAbs Therapeutics, Inc.

CD38 SADA

2nd SADA program



CD38; The Target

Target

- CD38 is a well characterized membrane associated target.
- Valid target - FDA has approved two monoclonal antibodies directed towards CD38 (isatuximab and daratumumab – both IgG-based technologies)

Expression

- Highly expressed in major Lymphoma indications (Both B- and T-cell origin) as well as Plasmacytomas and Myeloma

Development

- Potentially new way of addressing CD38 positive tumors – addition to the toolbox for physicians in particularly for the relapsed/ refractory setting.

The human CD38 mouse

Characterization and translational value

- Standard animal species do not bind anti-human CD38-antibodies
- License for a commercially available mouse model expressing human trangene CD38 under the murine CD38 promoter was obtained and bred for Y-mAbs by a commercial breeder (Taconic)
- Transgene (human CD38) expression was confirmed in peripheral blood cell as well as in lymphoid tissues – sufficient overlap with human expression pattern
- Based on the normal phenotype and overall relevant tissue binding of CD38-SADA, the model was considered a suitable model for assessing PK, toxicity and biodistribution to support human dosing

Status CD38 SADA Program – FiH protocol 1201

Non-clinical/ regulatory

- CD38 SADA non-clinical data package is estimated to be finalized Q1 2023
- Regulatory package is anticipated to be submitted H1 2023

Clinical

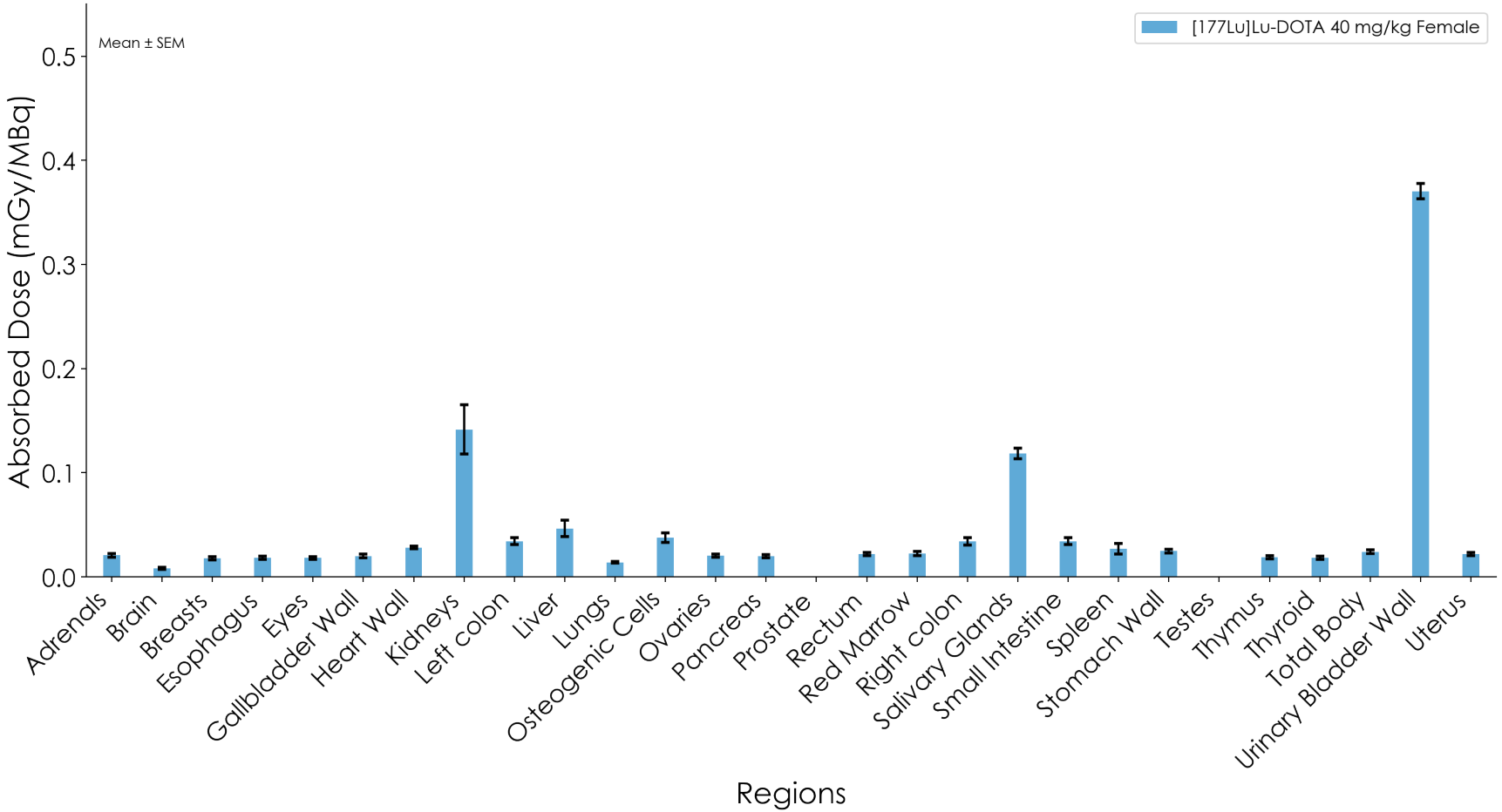
- FiH 1201 clinical protocol to explore safety and outcomes in adult patients in hematological indications known to be CD38 expressing
- Dosing of first patient estimated for end Q3, 2023

Program

- Stand alone protocol to establish PoC
- Program expected to be run in US

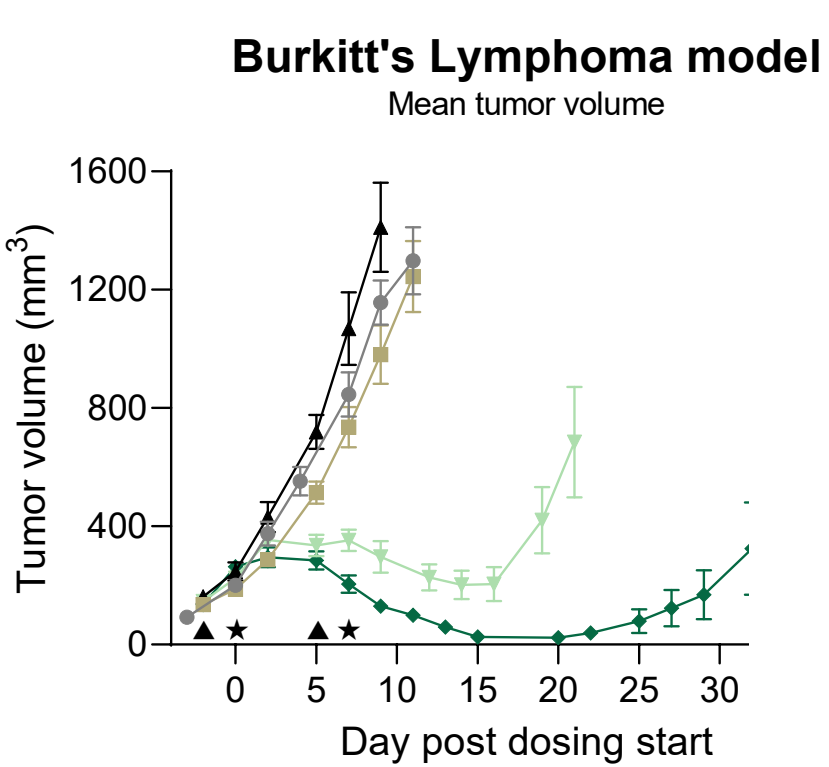
Human dosimetry predictions based on biodistribution in CD38-humanized mice

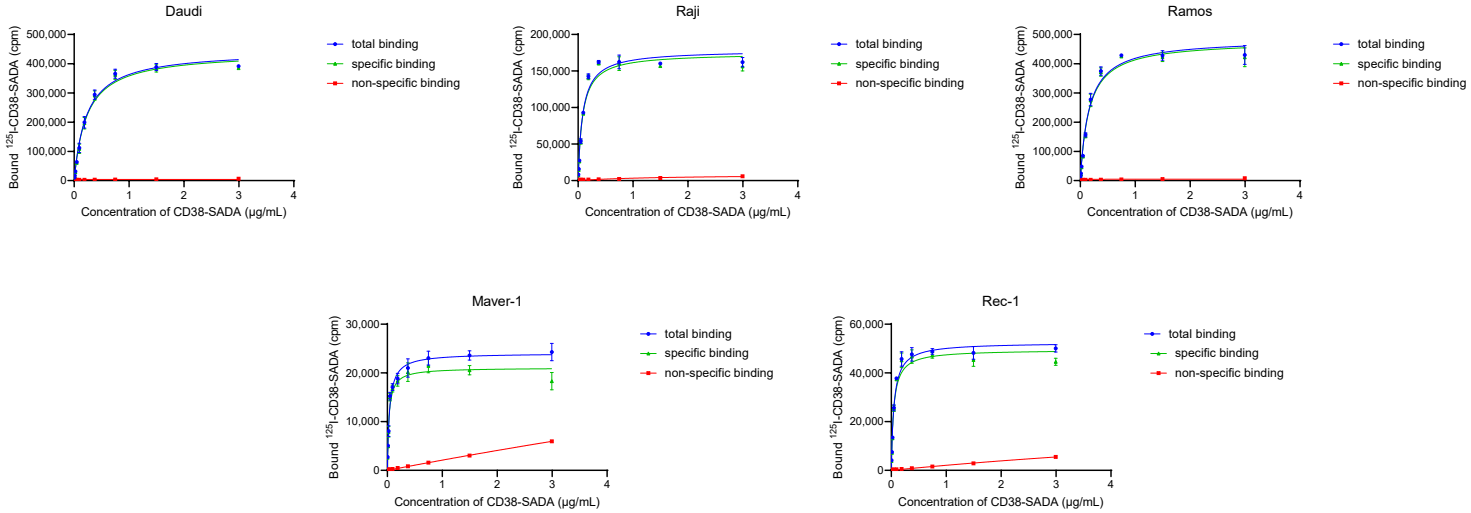
CD38-SADA dosed followed by 177Lu-DOTA with an interval of 48 hours



CD38-SADA:^{177}Lu-DOTA

Two cycles of CD38-SADA 48h prior to ^{177}Lu-DOTA, n=6-8





- Immunocompromised mice were inoculated subcutaneously with a human CD38+ Burkitt's Lymphoma cell line (Daudi)
- Two treatment cycles of CD38-SADA and ^{177}Lu-DOTA
- Anti-tumor response potentially correlated with ^{177}Lu-DOTA dose

Status SADA Programs - highlight

Clinical progress

- GD2 SADA – IND open, Project first patient dosed late Q4 2022 or early Q1 2023
- CD38 SADA – non-clinical investigations on track for Q4 finalization. Draft protocol expected end Q4. IND currently scheduled for H1 2023

Technology platform

- Further finetuning of SADA framework initiated

Areas to be explored include:

- Explore α-emitter using reference material; Proteus 1 and ^{225}Ac
- Evaluate ^{86}Yttrium – as PET emitter


THANK YOU

R&D Day

Dr V Rajah
Chief Medical Officer

Dec 14, 2022

Update on **DANYELZA®** (naxitamab-gqgk) in:

- Osteosarcoma
- Newly diagnosed high-risk neuroblastoma

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the compound and Y-mAbs.

GD2 expression in various cancers

Cancers	GD2 expression
Neuroblastoma[1,2]	~ 99-100%
Osteosarcoma[3,4]	~88%
Soft-tissue Sarcomas[5]	>90%
Triple Negative Breast cancer[6]	>50%

FDA approved in Nov 2020 in relapse/refractory high-risk neuroblastoma*

Investigational

For further clinical development.

Safety/efficacy have not been established by health authorities and not approved.

*** 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 is 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 benefit in a confirmatory trial(s).

1. Wu Z. Et al. Cancer Res. 1986; 46: 440–443.
2. Modak, S. Et al. Cancer Invest, 25: 67-77.
3. Heiner JP, et al. Cancer research 1987;47(20):5377-81.
4. Roth M, et al. Cancer 2014;120(4):548-54 doi 10.1002/cncr.28461.
5. Helena R. Chang, et al. Cancer, Aug 2, 2992, Vol 70, No.3
6. Ly S, et al. *J Immunother Cancer.* 2021;9(3).

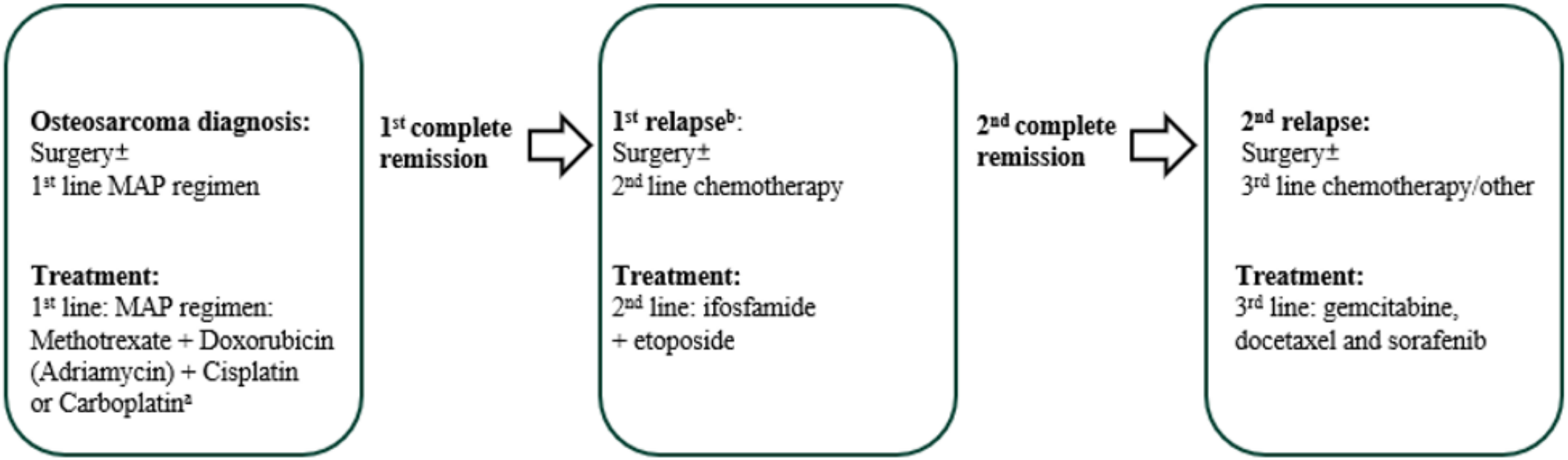
Why investigate Naxitamab in Osteosarcoma?

A strong unmet medical need

- Approximately **1,000 new patients each year** are diagnosed with osteosarcoma in each of the Regions: US, Europe and Asia[1] .
- **Multi-agent chemotherapy** was demonstrated to improve overall survival compared with surgery alone and is considered the **standard treatment** of osteosarcoma at time of diagnosis.
- Chemotherapy resistance and **relapsed disease** are **major obstacles** in treatment and prognosis of osteosarcoma. Despite patients being in surgical complete remission, a majority of patients will relapse due to **micrometastases** – most often pulmonary[2] .
- Patients with **recurrent osteosarcoma** have a **poor prognosis** with event-free survival (EFS) rates between 6% and 27%, and a **5-year post relapse survival rate of <20%**[3] .
- There have been no new chemotherapeutic, small molecule–targeted, or immunotherapeutic agents found to be active in osteosarcoma. As a result, **little improvement in the survival** for **more than 3 decades.**

1. Mirebello 2009, Xie 2014
2. Bielack 2005 and 2009
3. Meazza, Bastoni, and Scanagatta 2020

Overview of Osteosarcoma Treatment Cascade



Note:

[a] Can also be administered with ifosfamide (in children/young adults) or doxorubicin and cisplatin (in older adults);

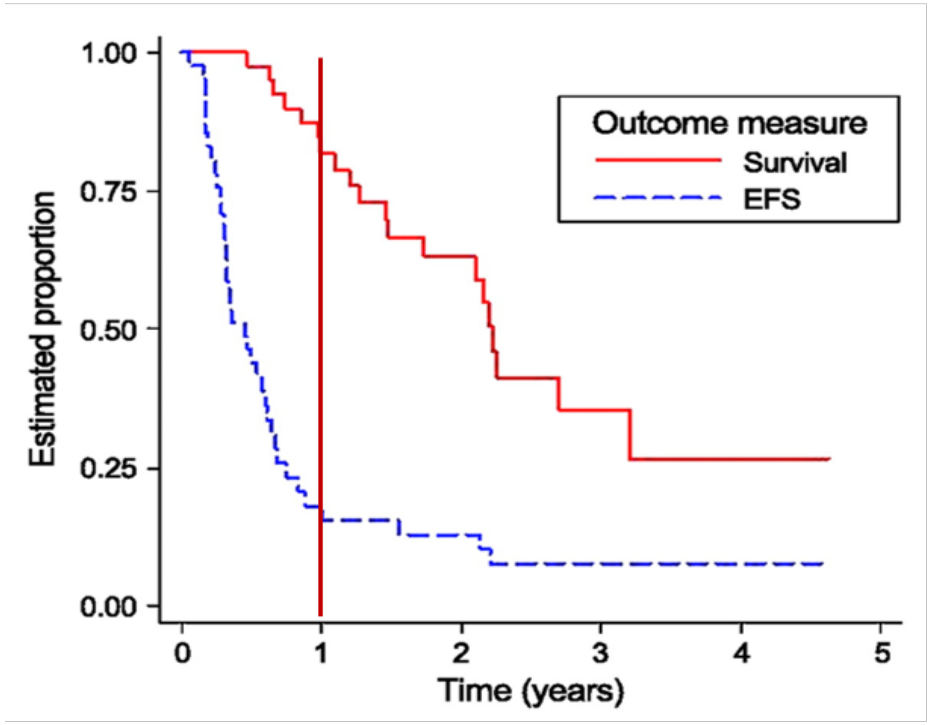
[b] 1st relapse is mostly to the lungs

References: Modified based on CSCO guideline 2020, NCCN 02.2022 and ESMO 2021 Strauss

Outcomes in key osteosarcoma trials AOST0221 & AOST1421

AOST0221

EFS_{12mo}: 20% (CI: 10 – 34%)

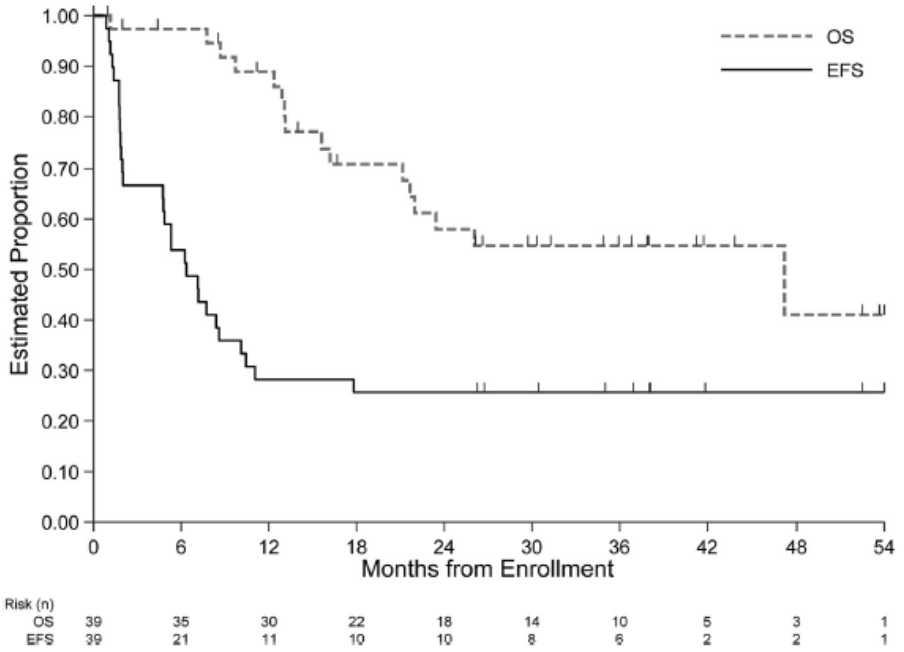


Arndt et al., (2015) Clin Cancer Res 16:4024

Pulmonary metastases. Inhaled GM-CSF

AOST1421

$DCR_{12\ mo}$	30.7%	(95% CI 17–47%)
$DCR_{2nd\ relapse}$ (n=28)	39%	(95%CI 21.7-56.5%)

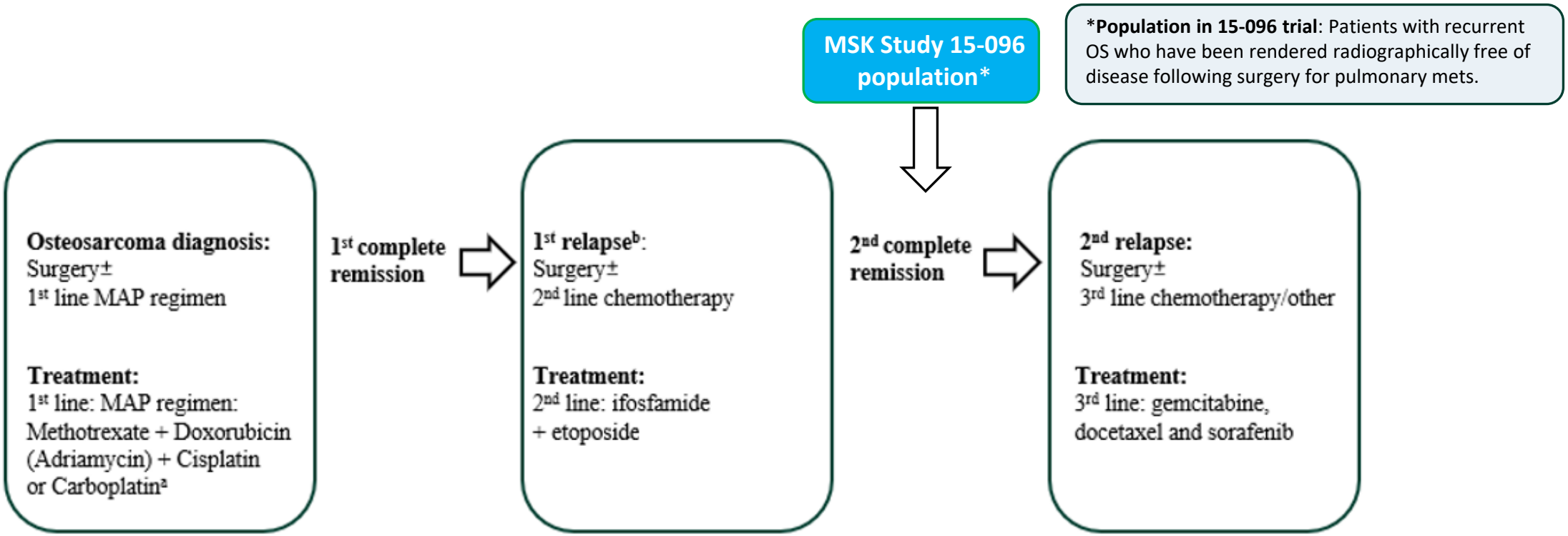


Hingorani 2022

Patients (n=39) with recurrent pulmonary mets treated with dinutuximab plus cytokine therapy as compared with a historical benchmark AOST0221

GM-CSF: Granulocyte-Macrophage Colony Stimulating Factor, EFS: Event free survival, DCR: Disease control rate

Overview of Osteosarcoma Treatment Cascade



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[b] 1st relapse is mostly to the lungs

References: Modified based on CSCO guideline 2020, NCCN 02.2022 and ESMO 2021 Strauss

Osteosarcoma – 15-096 Study (MSK)

Study:

- A **phase II study** of naxitamab with GM-CSF in the treatment of recurrent osteosarcoma in ≥ 2 CR

Recruitment status (Dec 1, 2022):

- 42 patients accrued (target 46):
  - **36** of whom represent 'pulmonary-only' relapse patients (the population that is relevant to address the primary objective of the study
  - Goal for accrual is **39** pulmonary-only' relapse patients
- Anticipate accrual completion by end Q1 2023

Participating centers:

- MSKCC, New York
- MD Anderson, Texas
- CHLA, Los Angeles

Primary Endpoint:

- EFS at 12 months in patients with pulmonary-only recurrence

Secondary Endpoints:

- Time to recurrence
- Overall survival
- Safety
- EFS at 12 months in patients with extra-pulmonary recurrence

Key Inclusion Criteria:

- Patients with recurrent OS
- Patients in ≥ 2nd complete remission
- >1 year of age and ≤ to 40 years of age
- Prior therapy: ≥ 3 weeks since last cytotoxic therapy, immunotherapy or radiation therapy.

Statistics:

- Assumptions:
  - 80% power to detect 12 months EFS with (naxitamab + SoC) of 50%.
  - H0: EFS < 30%. AOST0221– 20% (95% CI, 10-34%)

EFS: Event-free survival ; OS: osteosarcoma, CR: complete remission

MSK Study 15-096 – interim analysis Dec 2019

Patient characteristics (N=27):

Current Enrollment	27
Gender	
Male	19 (70%)
Female	8 (30%)
Race	
White	19 (70%)
Black	3 (11%)
Asian	2 (7 %)
Other	1 (5%)
Not Reported/Refused to Answer	2 (7%)
Age at Initial Diagnosis (Years)	
Mean	14.4
Median	13.7
Range	7.1 - 27.9
Age at Enrollment (Years)	
Mean	17.1
Median	15.7
Range	8.8 - 29.5
Extent of Disease at Diagnosis	
Localized	20 (74%)
Metastatic	7 (26%)
Site of Relapse	
Unilateral Lung	14 (52%)
Bilateral Lung	7 (26%)
Primary Site/Local Recurrence	3 (11%)
Non-Lung Distant Recurrence	3 (11%)
Prior Therapy	
Chemotherapy	27 (100%)
Surgery	27 (100%)
Radiation	2 (7%)

Summary of AEs related to Therapy (N=27):

Total Number of Adverse Events	218
Grade 1	97
Grade 2	71
Grade 3	47
Grade 4	3
Grade 1-2	168
Grade 3-4	50
Patients Evaluable for Toxicity	27 (100%)
# Patients with Grade 3 Tox	22 (81%)
# Patients with Grade 4 Tox	3 (11%)
# Patients with No Grade 3-4 Tox	5 (19%)
Mean age with Grade 3-4 Tox (Years)	16.9

[1]Interim safety data for Trial 15-096, (n=27):

- Toxicities were as previously reported for naxitamab:
  - Included pain, hypo- and hypertension, fever, nausea, and urticaria.
- No long term or delayed toxicities were observed.

1. Dela Cruz F, et al., SIOP Annual Meeting Poster Presentation, Lyon, France, 10/24/19.

Osteosarcoma – 205 Study (YmAbs) - overview

Y-mAbs Study :

- **Randomized, open-label, multi-national** phase II study in the treatment of recurrent osteosarcoma

Primary objective:

- To evaluate efficacy of naxitamab and chemotherapy, compared to chemotherapy only, assessed by DFS in patients in 2nd CR after resection of pulmonary metastases.

Global study with participation from:

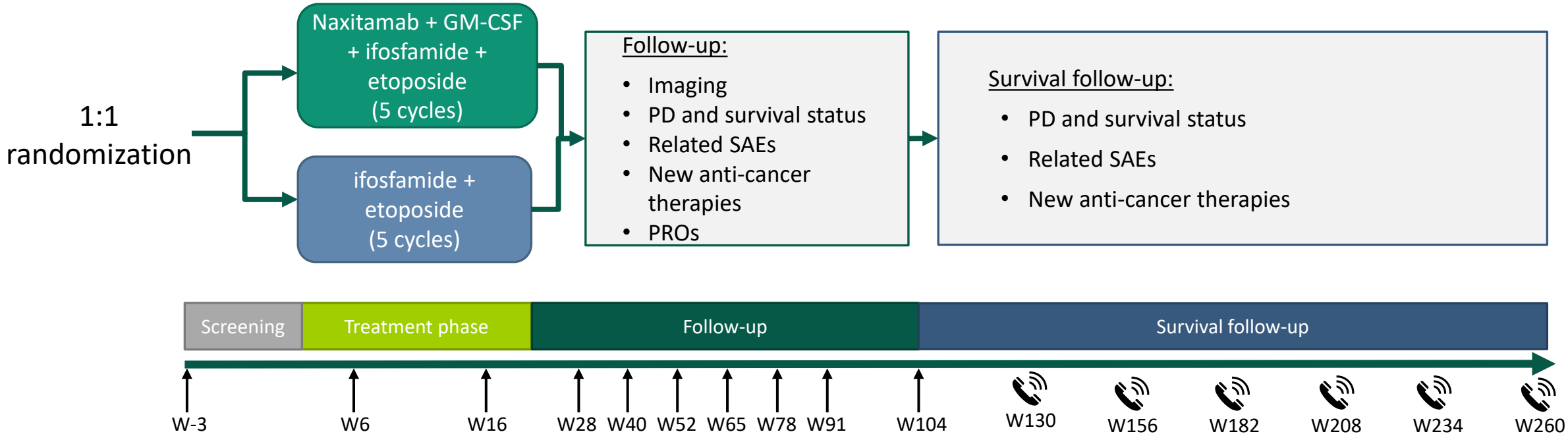
- US, Europe, China

Key milestones:

- IND submission – Q1 2023
- FPI – Q3 2023

DFS: Disease-free survival ; CR: complete remission; IND: Investigational new drug; FPI: First patient in

Osteosarcoma – 205 Study (YmAbs) – Study Design



Population:

140 subjects with osteosarcoma, in 2nd complete surgical remission after pulmonary metastases

Key Inclusion Criteria:

- Patients with pulmonary-only recurrence
- Patients in 2nd complete remission (after surgery)
- >1 year of age and ≤ to 40 years of age
- Prior therapy: ≥ 3 weeks since last cytotoxic therapy, immunotherapy or radiation therapy

Primary endpoint: DFS after 1 year

Secondary endpoints:

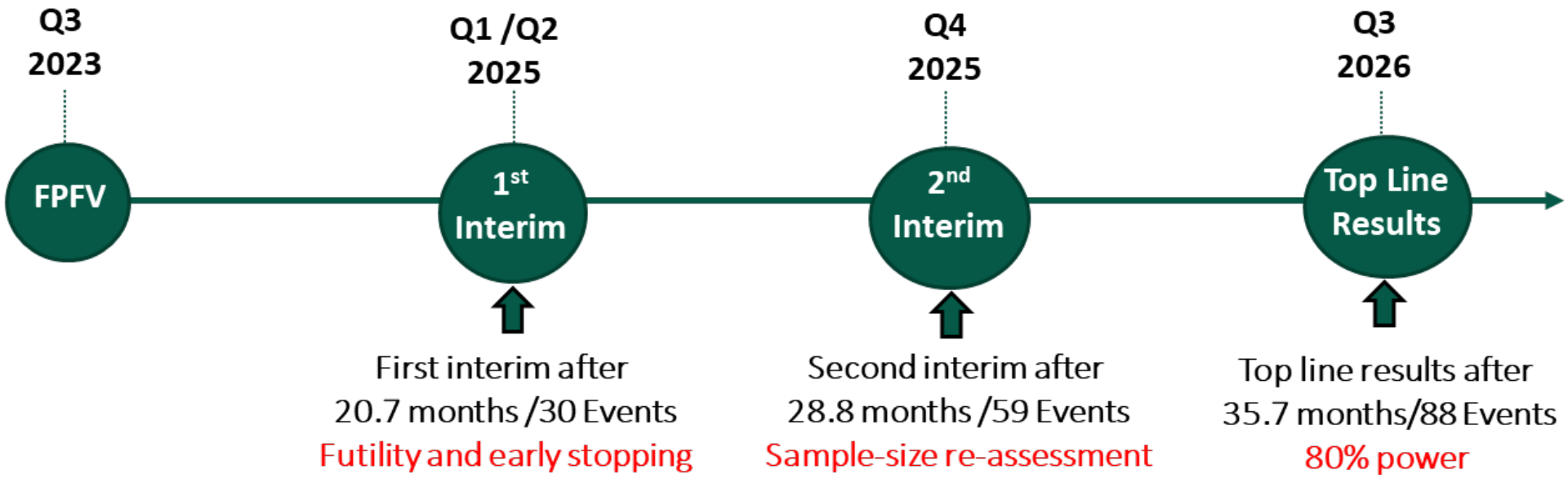
- Overall survival after 1 and 2 years
- DFS after 2 years
- Safety

DFS: Disease-free survival ; PRO, Patient reported outcomes; PD, Progressive disease

Survival follow-up Imaging

Estimated Timing of Interim analyses and Possibility of Early Reporting

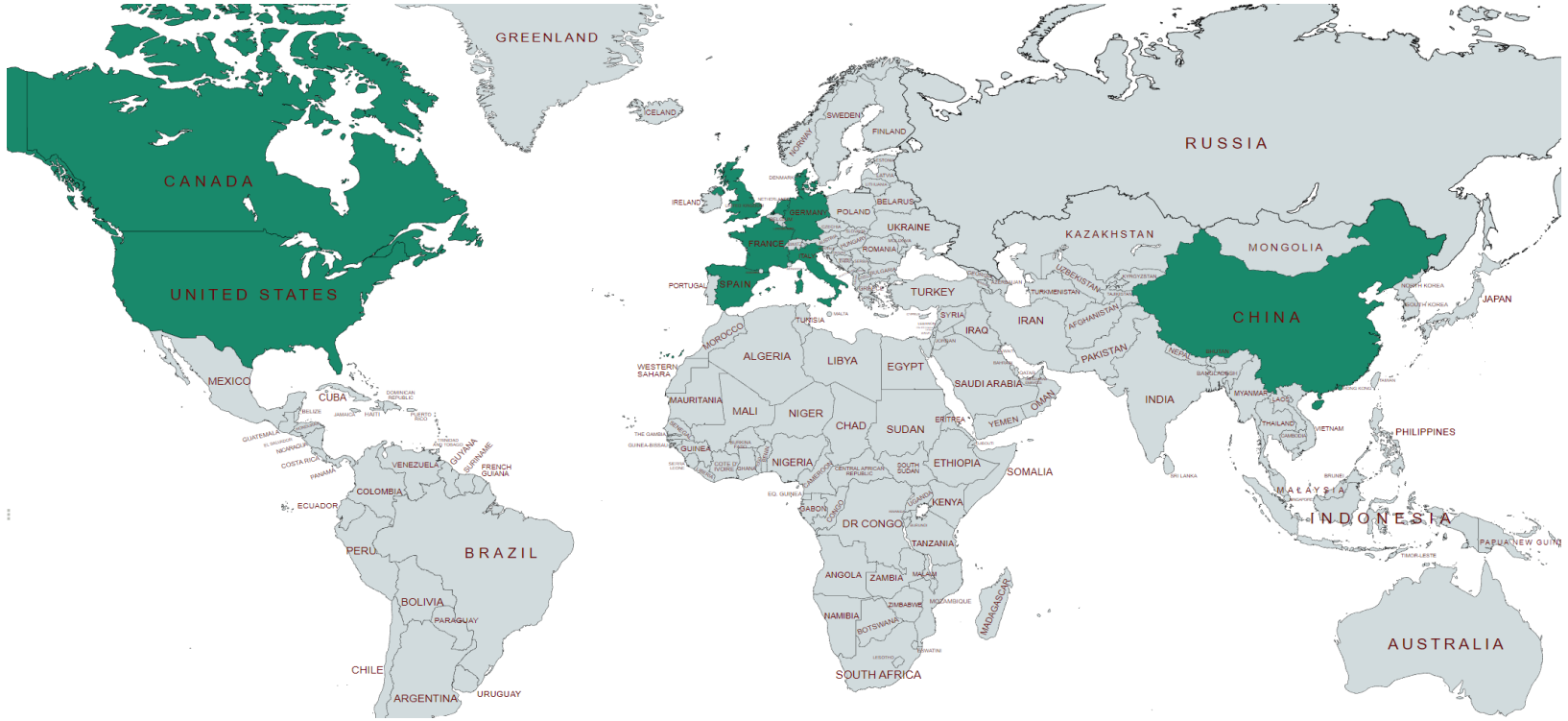
Sequential design, 1-year DFS, alpha 10%



FPFV; First patients first visit. DFS; Disease free survival

International participation - US, Europe, China (30% from each region)

Region	Countries	Patient allocation (%)
North America	**United States**	**30**
	Canada	5
Europe	**Germany**	6
	France	6
	Italy	5
	Spain	6
	Netherlands	4
	Denmark	3
	United Kingdom	5
Asia	**China**	25
	Hong Kong	5
	Total	**100**



Beat Childhood Cancer (BCC) Sponsored Study – Naxitamab in Induction treatment for newly diagnosed NB

International, Open-Label, Uncontrolled, Single-arm, Multicenter, Phase 2 Trial (NCT05489887)

Study	Phase II - Naxitamab Added to Induction Therapy for Subjects with Newly Diagnosed High-Risk NB
Design	• **5 cycles of chemotherapy* + NAXITAMAB + GM-CSF** (If ALK+: Ceritinib added) • If Poor response after 5 Cycles, 3 cycles of NAXITAMAB + salvage chemo
Study Objectives	**Primary:** To evaluate VGPR+ rate (VGPR + CR) and compare to historical controls **Secondary:** • ORR; ORR after 2 cycles • PFS and OS • Response rate of naxitamab + salvage in subjects with poor response after 5 cycles • Safety
Eligibility	**Key Inclusion:** • Newly diagnosed high risk NB • No prior systemic therapy • > 12 months ≤ 21 years of age
Sites	• Up to 50 sites in US & Canada
Sample size	• Target 76 patients; FPI: Sept 2022

Stats assumptions:

ANBL0532: 42% achieved VGPR or CR to standard induction

Null hypothesis: VGPR+ rate is ≤ 40%.

Stage 1: if ≥ 14 of initial 29 subjects achieve VGPR + -> stage 2 (enroll additional 47 subjects).

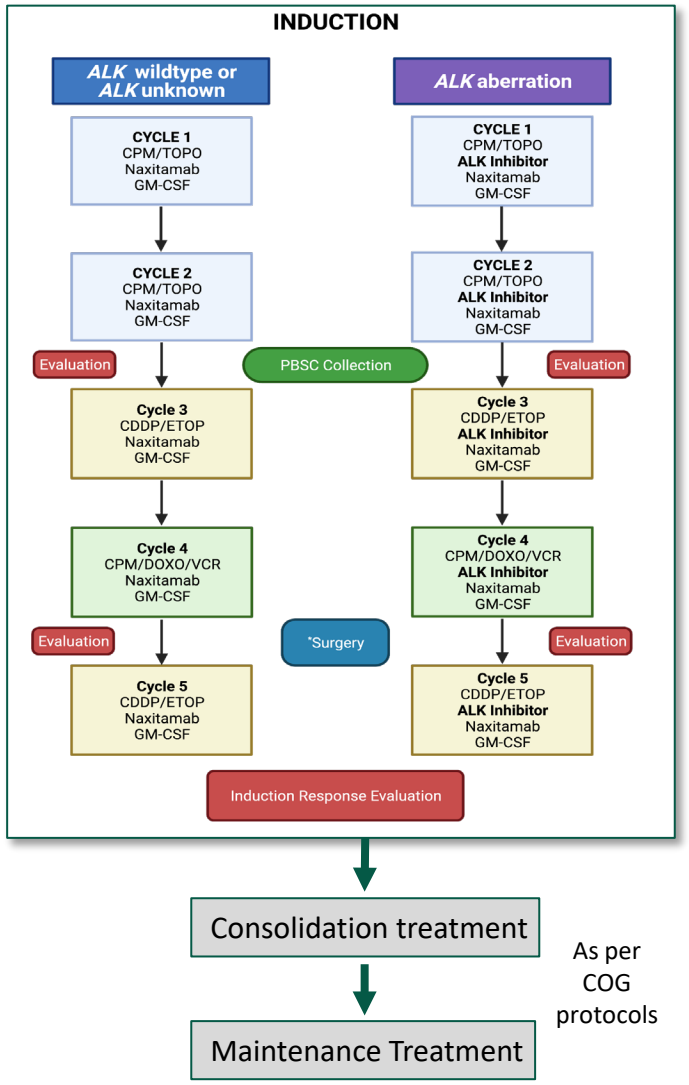
Stage 2: if ≥ 39 of 76 subjects achieve VGPR + the null hypothesis is rejected.

76 evaluable patients will yield 90% power to show at the one-side 2.5% level, that the VGPR+ rate is 60%.

* Cycle 1 + 2, topotecan + cyclophosphamide; Cycle 3, cisplatin + etoposide; Cycle 4, vincristine + doxorubicine + cyclephophamide; Cycle 5, cisplatin + etoposide;
ALK, anaplastic lymphoma kinase; CR, complete response; VGPR, Very Good Partial Response; MR, minor response; NR, no response; PR, partial response, PFS; Progression free disease

Beat Childhood Cancer (BCC) Sponsored Study – Naxitamab in Induction treatment for newly diagnosed NB

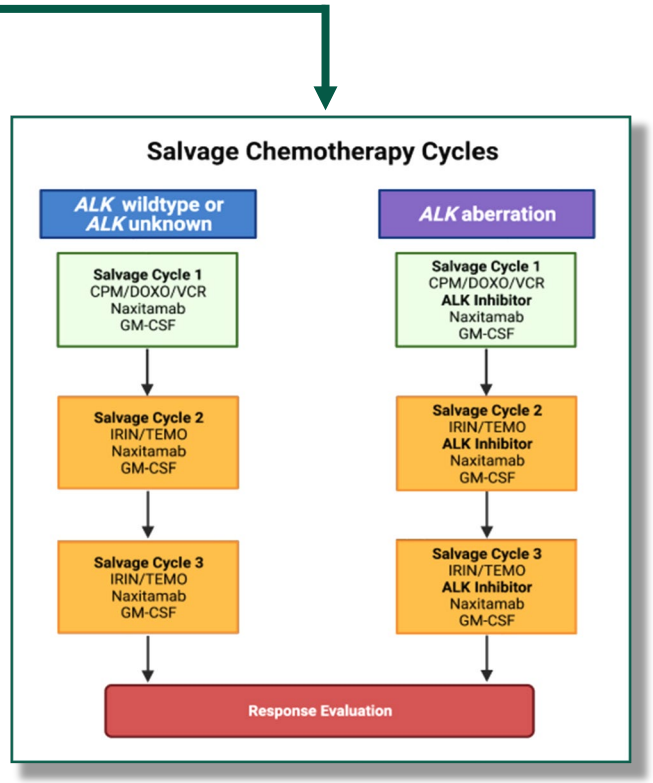
Study Design



As per COG protocols

If **poor response after Cycle 5** (PR/MR/NR):

- Additional 3 cycles of naxitamab + salvage chemo



* Cycle 1 + 2, topotecan + cyclophosphamide; Cycle 3, cisplatin + etoposide; Cycle 4, vincristine + doxorubicine + cyclephophamide; Cycle 5, cisplatin + etoposide;

ALK, anaplastic lymphoma kinase; MR, minor response; NR, no response; PR, partial response, CPM, Cyclephophamide; DOXO, doxorubicine; IRIN; irinotecan; TEMO, temozolomide; VCR, vincristine


THANK YOU