

Company Presentation

April 2020



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# **MISSION**



### Investment Highlights

Two pivotal-stage candidates – naxitamab and omburtamab – with BTD1

Rolling BLA<sup>2</sup> submission for naxitamab completed in March 2020 Rolling BLA submission for omburtamab to be completed in May 2020

Potential to expand into other indications and lines of therapy – studies ongoing

First BsAb product candidate in Phase 1/2 <sup>177</sup>Lu-omburtamab, our 2<sup>nd</sup> gen radioconjugate starting Phase 1/2 in Q2 2020

GD2-GD3 Vaccine - ongoing Phase 2 Study in high-risk NB patients in remission

Financial strength – secured financing through the end of 2022





<sup>&</sup>lt;sup>2</sup>BLA – Biologics License Application

# Strong Clinical Pipeline

Programs	Phase 1	Phase 2/Pivotal Study	Next Anticipated Milestones
Lead Development	Naxitamab (GD2) Lead Development		✓ Rolling BLA submission completed in March 2020
Candidates	<sup>131</sup> I-omburtamab (B7-H3)		Rolling BLA submission to be completed in May 2020
Vaccine	GD2-GD3 Vaccine		Multicenter Phase 2 study to open in 2020
Bispecific	GD2xCD3 - BsAb		In Phase 1/2 study since Q1 2019
Early Stage	<sup>177</sup> Lu-omburtamab		Study to open in Q2 2020

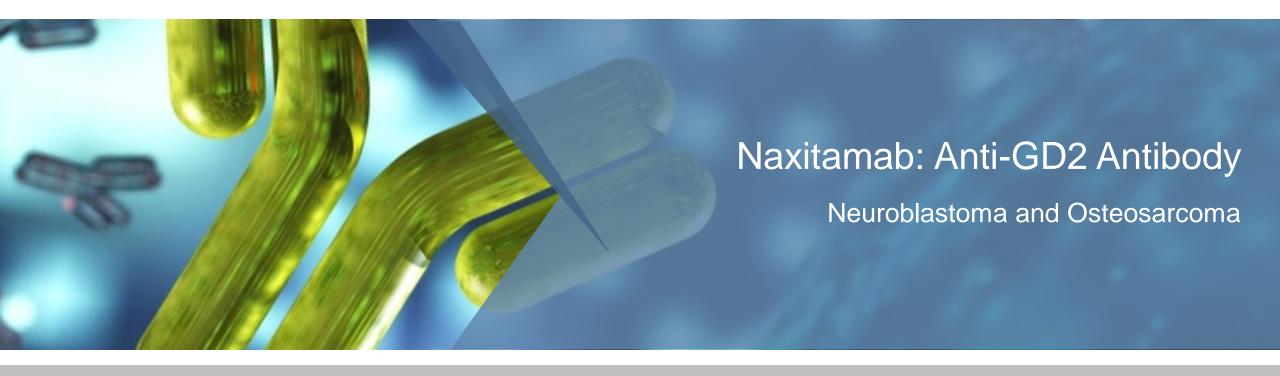


# Lead Development Programs Approaching Registration and Commercialization

Compound	Indication	Total Incidence per Year (US)	Addressable Patient Population per Year (US)
	Neuroblastoma – 2 <sup>nd</sup> Line	300	300
GD2 naxitamab	Neuroblastoma – Front Line	800	450
	Osteosarcoma – 2 <sup>nd</sup> Line	450	200
	Neuroblastoma Metastatic to the Central Nervous System (CNS/LM from NB)	80	80
B7-H3 omburtamab	Diffuse Intrinsic Pontine Glioma (DIPG)	300	300
	Desmoplastic Small Round Cell Tumors (DSRCT)	100	100







#### Primary and Secondary Refractory Patients – 2019 SIOP Presentations

Investigator evaluated responses

#### **Study 12-230 (SIOP October 2019)**

- 23 evaluable patients with primary refractory high-risk
   NB: 78% ORR
- 50% two-year progression free survival (PFS) was observed
- Study population of 35 patients with relapsed NB resistant to salvage therapy (Secondary refractory patients): 37% ORR
- 36% two-year progression free survival (PFS) was observed

#### Study 201 (dataset for BLA)

 Planned 24 patients to be included in BLA filing in March 2020: +70% ORR



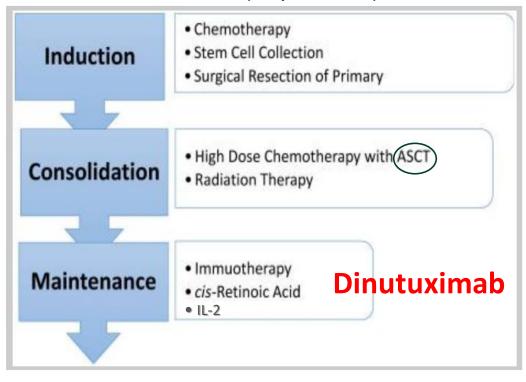
# Naxitamab Targets GD2 with Expanding Clinical Program

Naxitamab (GD2)	Phase 1	Phase 2/Pivotal Study	Highlights
Accelerated Dathway	Phase 2: Primary R/R High-Risk NB (Pediatric) – Study 201		Multi-center pivotal study per FDA; rolling BLA submission completed in March 2020
Accelerated Pathway	Phase 2: Primary R/R NB (Pediatric) – Study 12-230		Single-center study – part of rolling BLA pivotal data package
	Phase 2: Frontline High-Risk NB (Pediatric) – Study 16-1643		Ongoing Phase 2 study
Expanding to Frontline	Phase 2: Frontline naxitamab – Study 202		Frontline Phase 2 study to initiate in 2020
	Phase 2: Chemoimmunotherapy for R/R High-Risk NB – Study 17-251		Heavily pre-treated, high-risk NB patients
Label Expansion	Phase 2: Combo naxitamab plus chemo – Study 203		Combo Phase 2 study to initiate in 2020
	Phase 2: Relapsed Second-line Osteosarcom	a – Study 15-096	If successful, may form part of support for future sBLA in Osteosarcoma

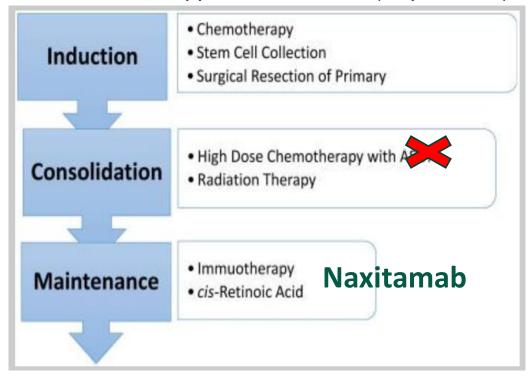


#### High Risk Neuroblastoma Treatment Recommendation – COG and MSK/Y-mAbs

COG – 8-20 h infusion (x4 per week)

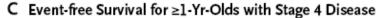


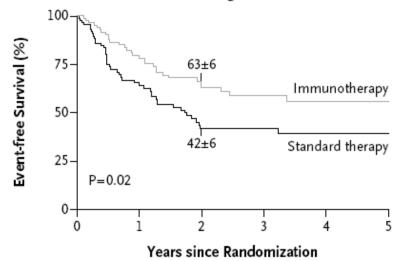
MSK/Y-mAbs – app 30 min infusion (x3 per week)



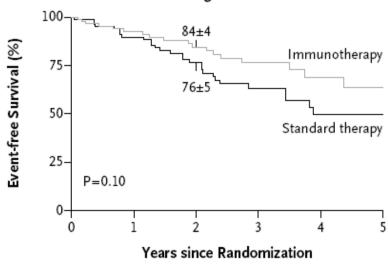
#### ORIGINAL ARTICLE

# Anti-GD2 Antibody with GM-CSF, Interleukin-2, and Isotretinoin for Neuroblastoma



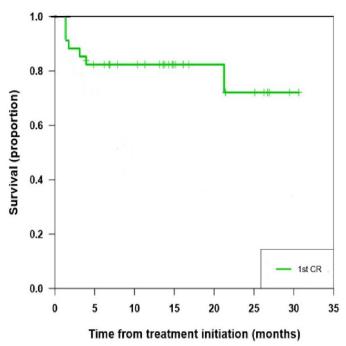


#### D Overall Survival for ≥1-Yr-Olds with Stage 4 Disease



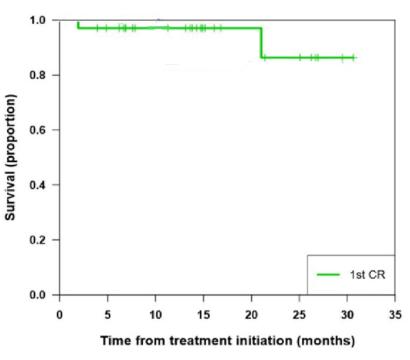
### Naxitamab: Frontline NB data without standard ASCT

#### 2-year Event Free Survival:



72.1% (95% CI = (53.1%,97.7%)) vs Dinutuximab 63%

#### 2-year Overall Survival:



86.3% (95% CI = (68.0%,100.0%)) vs Dinutuximab 84%

Data from Dr. J. Mora, Y-mAbs R&D Day Dec 11, 2019



#### Naxitamab: Key Takeaways

Addresses Significant Unmet Needs in R/R High-Risk NB • Potential to Expand to Broader Populations

Studies 12-230 and 201 formed primary basis of rolling BLA, which completed in March 2020

US commercialization in high-risk NB being planned for 2020

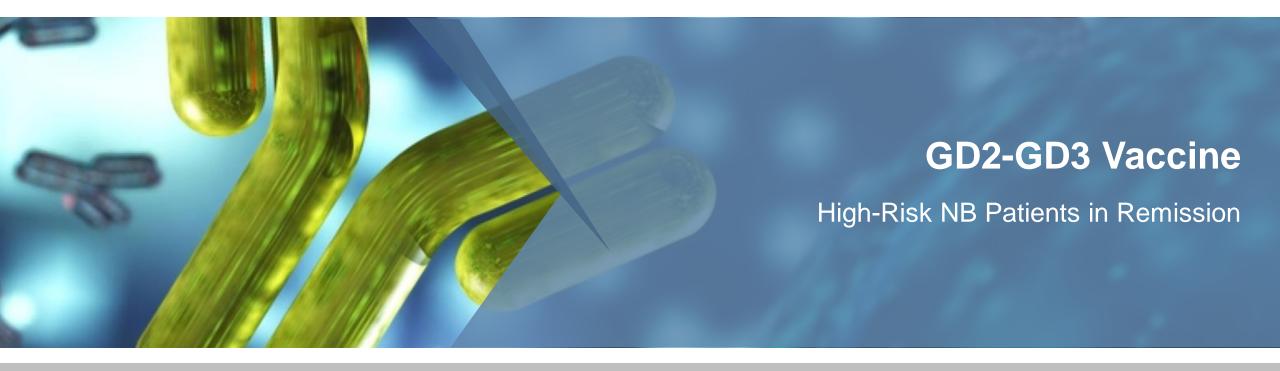
Granted ODD, BTD, and RPDD1

Multiple potential advantages over other GD2 targeting antibody-based therapies: Modest toxicity, shorter infusion time, ability to be administered in outpatient setting

<sup>1</sup>Indicates eligibility for a Priority Review Voucher (PRV) on approval







## GD2-GD3 Vaccine Update – A Naxitamab Add-On

Ongoing Phase 2 Study at MSK • Phase 1 Study Published in 2014 • First Phase 2 Study Data Published May 2018 at ANR



More than 230 patients on study drug – ODD granted – RPDD granted in 2019



84 high-risk NB patients received the GD2-GD3 Vaccine, all of whom were in second or later remission



PFS of approximately 51% and OS of approximately 90% at two years



Study now also enrolling patients in first remission

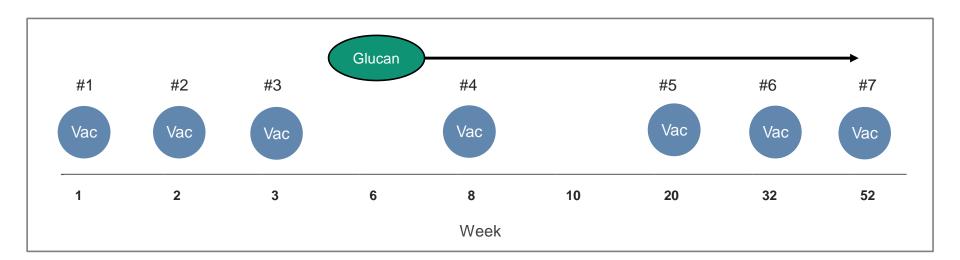


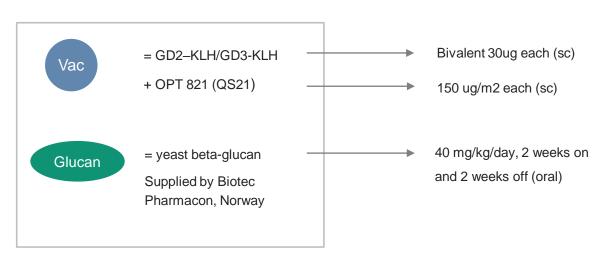
The GD2-GD3 Vaccine appears to be well tolerated, with no reported grade 3 or grade 4 toxicities

# Phase 2 Vaccine Study at Memorial Sloan Kettering

Clinicaltrials.gov NCT00911560

7 cycles





Seroconversion = antibody response		
% patients with positive		
	Anti-GD2 titer	Anti-GD3 titer
Pre-vaccine	13.3%	29.4%
During vaccine/follow-up	82.7%	70.4%

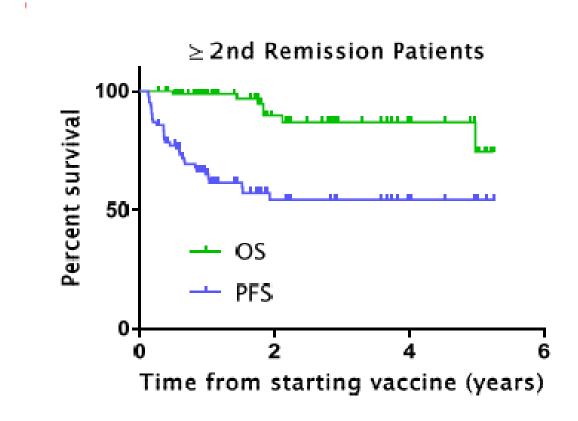
I. Cheung et al., Phase II Trial of GD2-KLH/GD3-KLH Vaccine for Stage 4 Neuroblastoma in 2<sup>nd</sup> or later Remission ANR, San Francisco, May 2018



### Focus on 2<sup>nd</sup> and Later Remission Group

Y-mAbs GD2-GD3 Vaccine multi-center study

Study 601 – NB patient 2<sup>nd</sup> CR



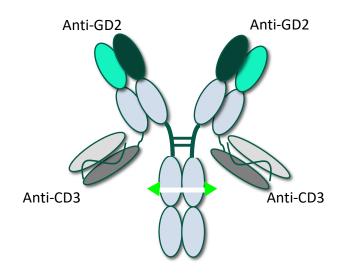
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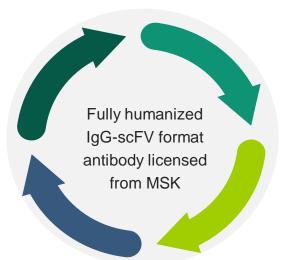






### Bispecific GD2 Antibody – Planning for three Phase 2 studies





Phase 1/2 clinical dose escalation study ongoing since Q1 2019 – at Cohort 6 recruiting patients with:

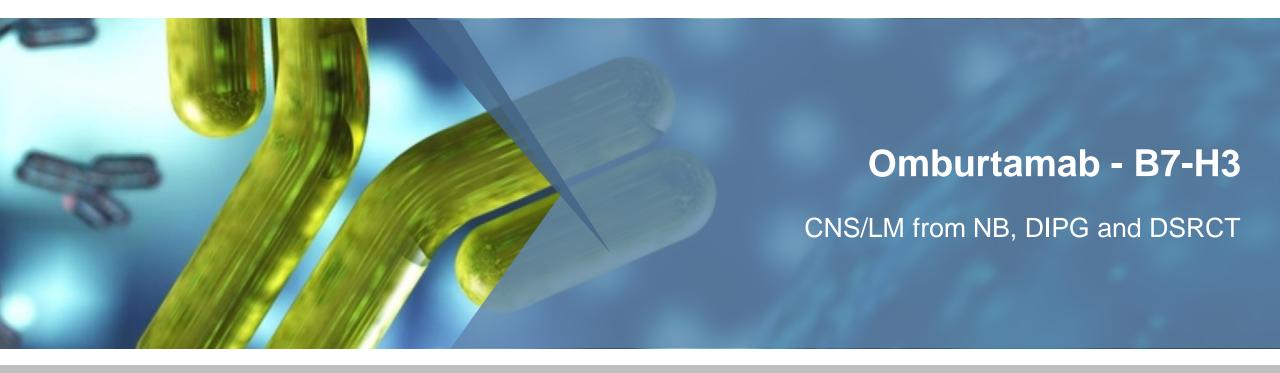
- R/R NB
- High grade Osteosarcoma
- Other GD2(+) solid tumors, where patients have relapsed or refractory disease that is resistant to standard therapy



Adult patient population also targeted

- 1) Phase 2 in SCLC IND submission planned for Q4 2020. Multicenter Study 402
- 2) Phase 2 in 3rd line NB Based on MSK legacy Study 18-034 in GD2+ tumors
- 3) Phase 2 in refractory Osteosarcoma Based on MSK legacy Study 18-034 in GD2+ tumors





### Omburtamab Clinical Platform

Omburtamab B7-H3	Phase 1	Phase 2/Pivotal Study	Highlights
Accelerated	Phase 2: CNS/LM from NB (Pediatric) – S	tudy 101	Multi-center PK study; Rolling BLA submission completed by May 2020
Pathway	Phase 1: CNS/LM – Study 03-133		MSK single-center efficacy data
	Phase 2: DIPG multi-center - Study 102		Multi-center study to initiate in 2020
Label Expansion	Phase 1: DIPG – Study 11-011		Study update presented at ASCO 2019
	Phase 2: DSRCT – Study 19-182		Study update from Phase 1 presented at CTOS Nov 2019



## Omburtamab Regulatory Path to BLA Approval

#### Regulatory

Studies 03-133 and 101 to form basis of BLA submission:
OS data accepted by FDA for accelerated approval
PK and dosimetry comparison required

Data from Study 101 multicenter will support BLA submission

Qualifies for accelerated approval

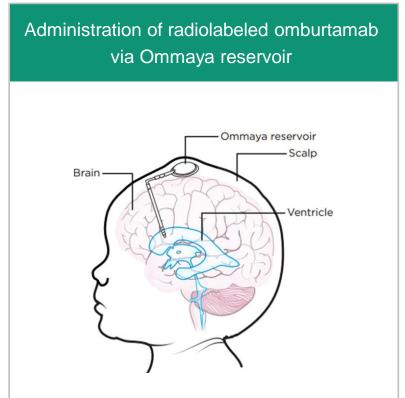
BLA submission planned to be completed by May 2020

ODD, BTD, and RPDD

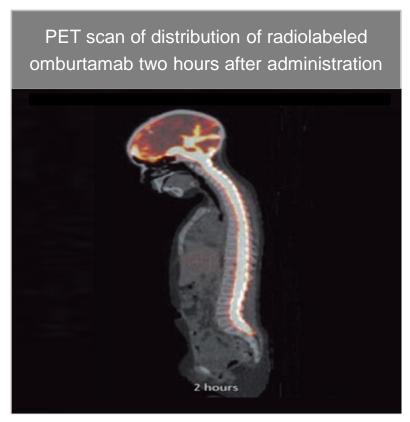


### Omburtamab: Delivered in an Outpatient Setting – 2 Doses per Patient

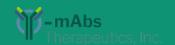
CNS/LM from NB patients





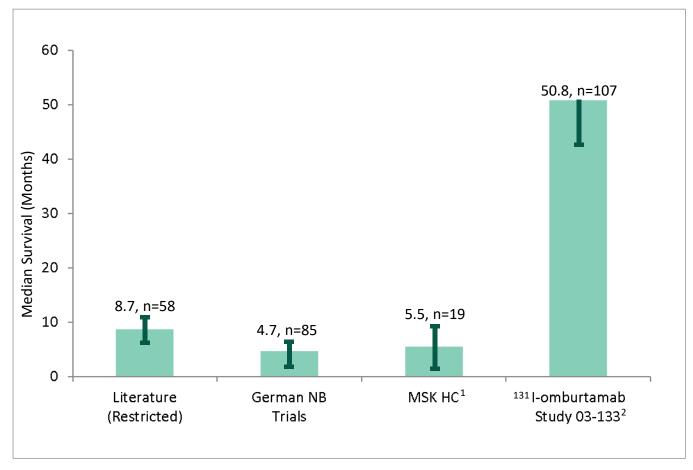


After induction treatment including all or some of the three treatments (chemotherapy, surgery, and radiation) patients will receive radiolabeled omburtamab



#### Omburtamab: Clinical Overview

Study 03-133: <sup>131</sup>I-omburtamab Improves Survival in CNS/LM from NB Patients



These results demonstrate the opportunity for <sup>131</sup>I-omburtamab to address the lack of an established, effective therapy for patients with CNS/LM from NB

<sup>&</sup>lt;sup>2</sup> <sup>131</sup>I-omburtamab = Patients with CNS/LM treated under Study 03-133



<sup>&</sup>lt;sup>1</sup> MSK HC = neuroblastoma patients with CNS/LM treated at MSK prior to 2003

#### Omburtamab: Key Takeaways

Addresses Significant Unmet Needs and has the Potential to Expand its Application to Broader Populations

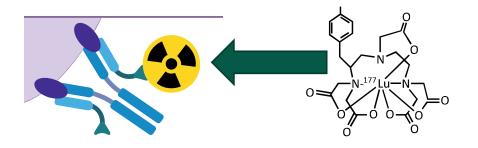
- No approved products for patients with R/R NB who have CNS/LM from NB
- · Goal of treatment is generally palliative

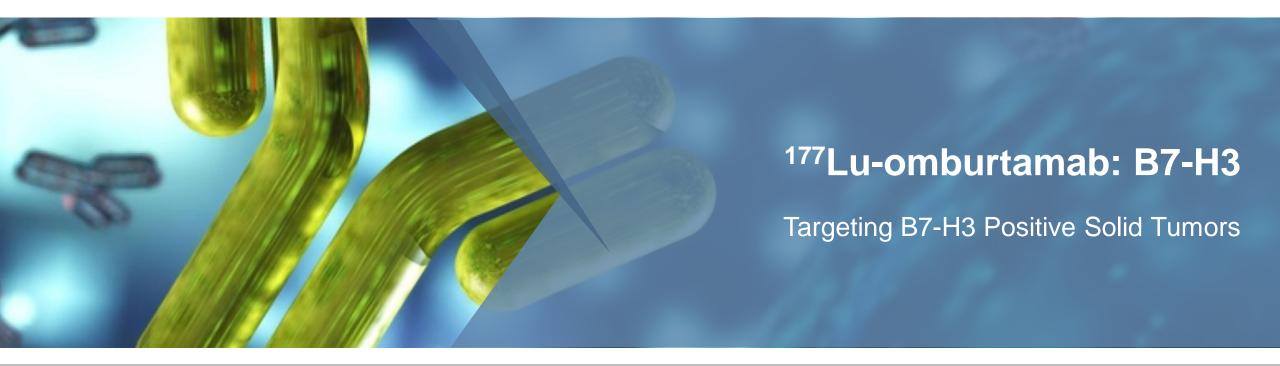


- Historical median OS of ~six months and no expected five-year survival
- Granted ODD, BTD, and RPDD; May qualify for a sBLA for DIPG and DSRCT assuming positive pivotal data
- Studies 03-133 and 101 to form primary basis for rolling BLA submission for CNS/LM from NB - expected to be submitted in May 2020
- Large potential market opportunity for the treatment of LM from tumors expressing B7-H3









# <sup>177</sup>Lu-omburtamab - Pediatric and Adult Strategy

#### **Adult**

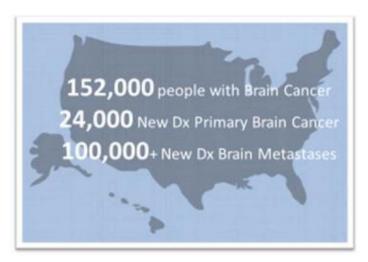
- First indication: **Basket study** of B7-H3 positive CNS/LM tumors
- Prior experience from compartmental treatment of adult patients with <sup>131</sup>I-omburtamab

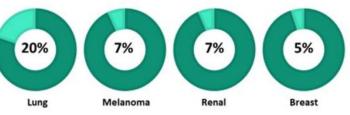
#### **Pediatric**

- First indication: Medulloblastoma
- Prior experience from compartmental treatment with <sup>131</sup>I-omburtamab – 27 pediatric patients treated
- IND submitted Dec 2019

Clinical Testing (Adult)

- Experience using <sup>131</sup>I-omburtamab in 68 patients with tumors such as sarcoma, melanoma and medulloblastoma
- Animal toxicity studies of completed on GLP material
- cGMP production established

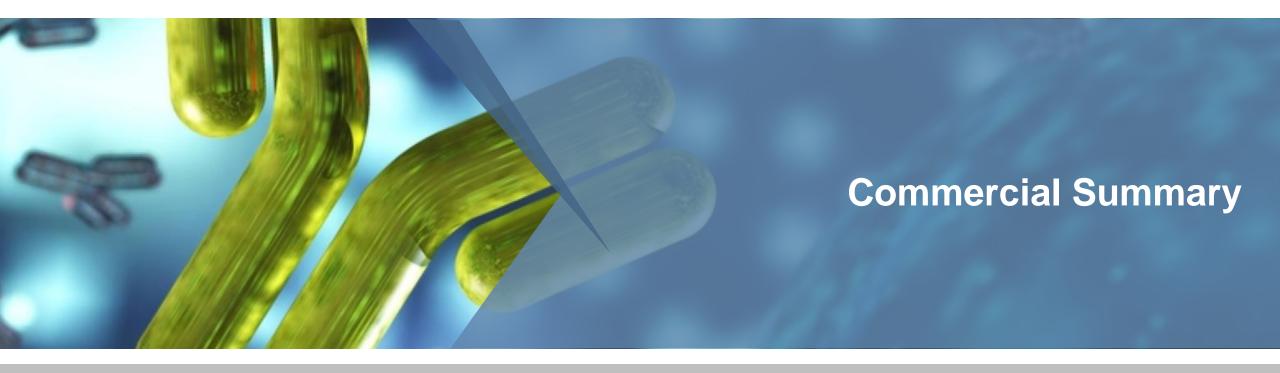




Incidence of Brain Metastases - Top 4 Tumors

SURVIVAL		
Primary Tumor 5 Years	32.9%	
Metastatic	3-6 months	





#### In preparation for launch, commercial activities focused on three key areas:

Build best in class, right-sized commercial organization

- Small universe of pediatric cancer centers treat majority of neuroblastoma
- Lean and efficient commercial organization to align with targeted launch

Launch planning and execution focused on driving:

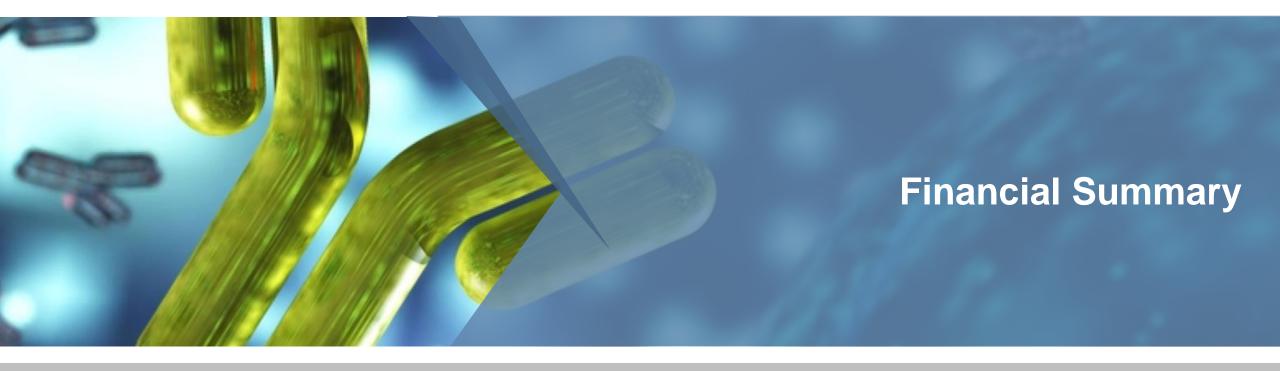
- Rapid uptake at launch
- Optimal pricing and reimbursement coverage
- Supportive stakeholder experience along neuroblastoma treatment journey

Building awareness of Y-mAbs

- Outreach & engagement with KOLs and top pediatric cancer centers
- Engagement with key neuroblastoma advocacy groups
- Increased medical congress presence to raise profile of Y-mAbs







## Strong Financial Position with Blue Chip Investors

Y-mAbs Has Completed a Series of Successful Financing Rounds, with \$374 Million Raised to Date





IPO – September 2018 \$110 Million

Follow on: November 2019 \$144 Million



\$374 Million
Raised to Date

#### \$207 Million

of cash and cash equivalents as of January 1, 2020



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