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¹³¹I-Omburtamab

- Regulatory filing update
- Study 101 update



¹³¹I-Omburtamab - BLA and MAA submission timelines

FDA:

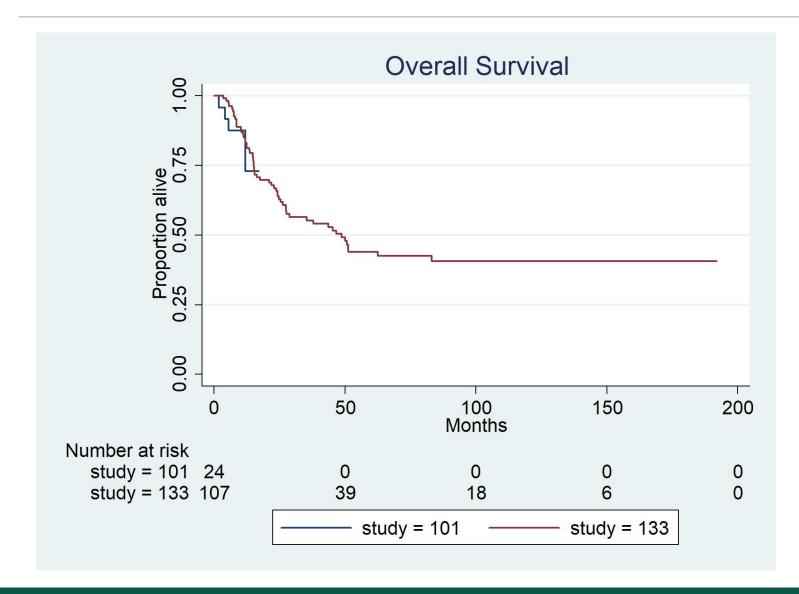
- Y-mAbs is in close discussions with the FDA. Final agreement on content of the BLA package that will enable filing, is anticipated in early Jan 2021.
- We estimate submission of the file shortly after reaching an agreement with the FDA.

EMA:

- A PIP for ¹³¹I-Omburtamab in CNS neuroblastoma has been agreed and validated by the PDCO.
 Furthermore, Y-mAbs has had a promising and informative meeting with the EMA in Nov 2020.
- Y-mAbs intends to proceed with the filing of the MAA as planned in Q1 2021.

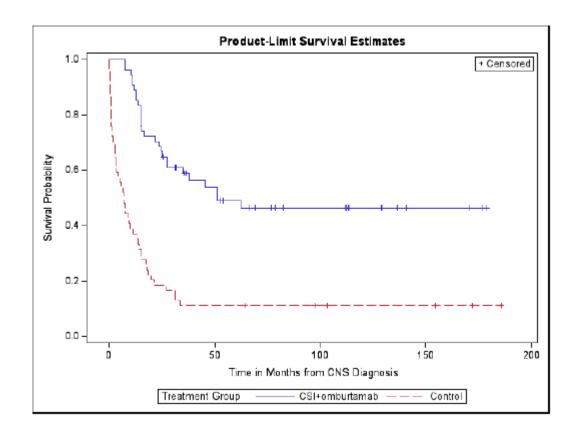


¹³¹I-Omburtamab - Results from the multicenter trial **Trial 101**



Results confirm the improved outcomes observed in MSK trial 03-133

¹³¹I-Omburtamab – Preliminary results of Propensity score on Trial 03-133 vs CGCCR



n=54 subjects in both groups

In the set of matched subjects, 3 year survival was greater in the CSI+omburtamab subjects, than in the external control subjects

Table 3. Survival results for matched subjects.

P arameter	03-133 CSI+omburtamab (n=54)	CGCCR (n=54)	p-value ¹
3 year survival proportion (95% CI)	0.59 (0.44, 0.71)	0.11 (0.05, 0.21)	<0.001

¹p-value from proportional hazards model with robust variance estimator



¹³¹I-Omburtamab - Independent radiographic evaluation of tumor response from **Trial 101**

Number of patients in the full analysis set	24	
Objective Radiographic Response (CR and PR), N (%)	4 (40.0)	
[95% CI*]	[12.2; 73.8]	
Best Overall Radiographic Response		
Complete response	2 (20.0)	
Partial response	2 (20.0)	
Stable disease	5 (50.0)	
Progressive disease	1 (10.0)	
Total	10 (100.0)	
No evidence of disease / Not evaluable (N)	14	
N: Number of subjects, %: Percentage of subjects		
Best overall radiographic response is assessed at Week 26 by independent review of images.		

Results confirm the direct antitumor effect of 131I-omburtamab

Disease Control at Week 26 in 9 out 10 pts (90%)





Naxitamab

Osteosarcoma

Study15-096: A phase II study of humanized monoclonal antibody 3F8 (Hu3F8) with granulocyte-macrophage colony stimulating factor (GM-CSF) in the treatment of recurrent osteosarcoma



Naxitamab in Osteosarcoma – Study 15-096 - Trial status, patient accrual & new sites initiated

As of December 2, 2020: 33 total patients accrued (target: 39)

Patient Accrual:

Year	Pt Enrolled
2015	6
2016	4
2017	4
2018	9
2019	6
2020	4

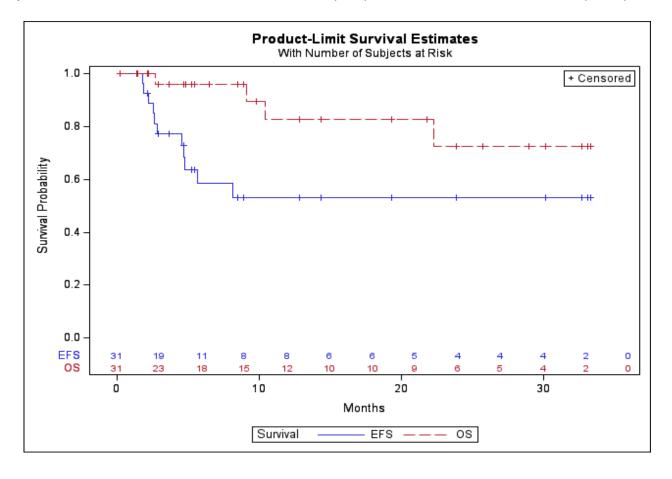
New sites:

- MD Anderson: IRB approved and site initiated on 14-Dec-2020 and expected to start enrolling patient in Jan-2021
- CHLA: IRB approved and site initiated on 03-Dec-2020 and expected to start enrolling patient in Jan-2021



Baseline characteristics	N (%)	
Full analysis set (N)	31	
Gender		
Male	21 (68%)	
Female	10 (32%)	
Race		
White	23 (74%)	
Black	3 (10%)	
Asian	2 (6%)	
Other	1 (3%)	
Not reported	2 (6%)	
Age at initial diagnosis (Years)		
Mean (SD)	14.3 (5.2)	
Median (Min; Max)	17 (8;29)	
Extent of disease at diagnosis		
Local	23 (74%)	
Metastatic	6 (19%)	
Not reported	2 (6%)	

Kaplan-Meier curves of overall survival (OS) and event-free survival (EFS) – Study 15-096



Naxitamab in Osteosarcoma – Study 15-096 – Adverse Events

Treatment emergent adverse events	Grade 3 and 4 adverse events N (%)
Safety Analysis Set (N)	31
Pain	11 (35%)
Hypotension	7 (23%)
Hypertension	5 (16%)
Hypophosphatemia	3 (10%)
Urticaria	2 (6%)
Vomiting	2 (6%)
Hypokalemia	2 (6%)
Lymphocyte count decreased	2 (6%)
Hyponatremia	2 (6%)
Neutrophil count decreased	2 (6%)
Dyspnea	1 (3%)
Fever	1 (3%)
Hyperglycemia	1 (3%)
Nausea	1 (3%)
Hypocalcemia	1 (3%)
Platelet count decreased	1 (3%)
Allergic reaction	1 (3%)
White blood cell decreased	1 (3%)
Alanine aminotransferase increased	1 (3%)
Sinus tachycardia	1 (3%)
Lipase increased	1 (3%)
Dehydration	1 (3%)
Adult respiratory distress syndrome	1 (3%)
Anaphylaxis	1 (3%)
Apnea	1 (3%)
Aspartate aminotransferase increased	1 (3%)
Chills	1 (3%)
Hypermagnesemia	1 (3%)
Hypoxia	1 (3%)
Pancreatitis	1 (3%)
Rash maculo-papular	1 (3%)
Stridor	1 (3%)





Nivatrotamab (GD2xCD3)

Study 18-034: Phase I/II study of humanized 3F8 bispecific antibody (Hu3F8 BsAb) in patients with relapsed/refractory neuroblastoma, osteosarcoma, and other GD2(+) solid tumors



Clinical Experience for Nivatrotamab (18-034)

Clinical experience with nivatrotamab is derived from the first-in-human (FIH) clinical trial (no.18-034, ClinicalTrials.gov id: NCT03860207).

As of October 2020:

- 10 patients have been administered 6 dose levels of nivatrotamab, ranging from 0.0045 mcg/kg/dose to 8 mcg/kg/dose and 0.009 to 9.3 mcg/kg/cycle via IV administration.
- Two dose administrations per cycle were applied using a low priming dose and a subsequent treatment dose. The priming dose was set to 1.3 mcg/kg/dose.
- No dose-limiting toxicities (DLTs) were observed in dose levels 1 to 5 where in total 7 patients were exposed with maximum dosing of 4.8 mcg/kg/cycle in these patients. The maximum single exposure in the first 5 dose levels was 245 mcg therapeutic dose or 336 mcg total dose per cycle (at dose level 5).
- Additionally, 3 patients were dosed at dose level 6, dosing patients up to 9.3 mcg/kg per cycle. Two patients experienced
 DLTs at dose level 6, and the study is planned to continue with increased steroid pre-medication at a lower dose level.
- No current reports of CR or PR from the patients enrolled so far.



Nivatrotamab (GD2xCD3) In SCLC

Study 402: Safety and clinical activity of nivatrotamab, an anti GD2×CD3 bispecific antibody, in relapsed/recurrent metastatic small-cell lung cancer - An open-label, single-arm, multicenter, phase 1/2 trial



SCLC - The Disease

Anti-GD2xCD3 in adults with relapsed SCLC -10/10 pts aGD2 binding

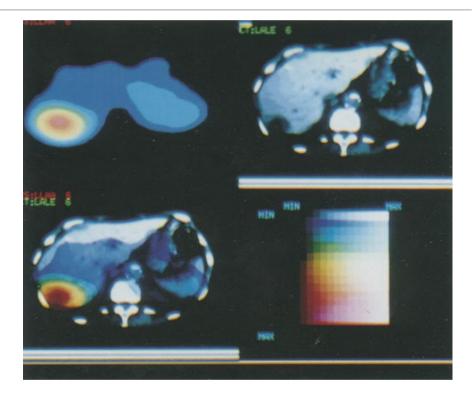
- •Lung cancer is comprised of non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Small cell lung cancer which constitutes about 13-15% of lung cancers is biologically and clinically distinct from non-small cell cancer.
- •App 225.000 new cases and 135.000 deaths per year in US
- •It is on a spectrum of neuroendocrine cancer that express the disialoganglioside GD2. Clinically SCLC is more malignant than NSCLC with a rapid doubling time, early metastasis to the liver, brain and bone. SCLC respond rapidly to cytotoxic treatment however develop fast resistance to therapy.

The prognosis for patients with SCLC is dismal despite improvements in diagnosis and therapy made during the past 25 years. Without treatment, SCLC has the most aggressive clinical course of any type of pulmonary tumor, with median survival from diagnosis of only 2 to 4 months. The overall survival at 5 years is 5% to 10%.

SCLC – GD2 expression

Anti-GD2 in SCLC patients showed 10/10 pts with aGD2 binding – also in liver metastasis

Patient number	Previously identified sites	Identified by 3F8 scan		
1	Right diaphragm (CT)	Yes		
	Right hilar, mediastinal adenopathy (CT)	Yes		
	T8 vertebra (BS)	Yes		
2	Shaft of right femur (BS)	Yes		
	Right mid-lung mass with right paratracheal and superior mediastinal			
	adenopathy (CT)	Yes		
3	Left upper lobe mass involving the left hilum (CT)	Yes		
4	Mass involving left mid and upper lung fields involving the left hilum			
	with extensive mediastinal adenopathy (CT)	Yes		
	Proximal right femur (BS)	Yes		
	Left iliac crest (seen on BS, not confirmed radiologically)	No		
5ª	Right medial lung mass (CXR)	Yes		
	Diffuse liver involvement (CT)	Yes		
6	Superior segment right lower lobe with			
	right hilar and mediastinal adenopathy (CXR)	Yes		
7	Left perihilar mass, hilar adenopathy (CXR)	Yes		
8	Right pulmonary mass with right hilar and mediastinal adenopathy (CT)	Yes		
9	Right upper lobe mass, hilar and mediastinal adenopathy (CT)	Yes		
	Multiple small brain metastases (CT)	No		
10	Right hilar mass with hilar and mediastinal adenopathy (CT)	Yes		
	Multiple liver metastases (CT)	Yes		



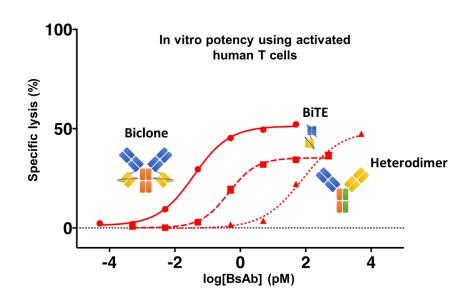
Color-enhanced SPET image (topleft) and CT scan image (top right) of the patient demonstrates the excellent localization to tumor sites. According to the scale used, red represents the greatest intensity of SPET signal. Shown below the two separate images is a fused SPET/CT scan image confirming the precise localization of the antibody to the single liver metastasis, seen as a large lesion, black in color, on the CT scan slice. Similar fusion images were produced for other liver metastases Grant et al., Eur J Nucl Med (1996) 23:145-149



Bispecific Antibody Platform

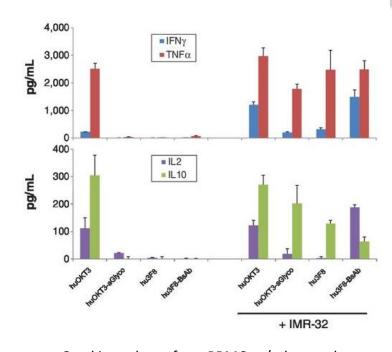
huGD2-BsAb have bivalent binding

Significantly higher potency

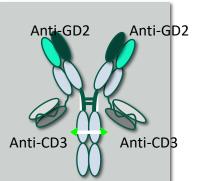


Adapted from Santich BH et al. Adv Neuroblastoma Res 2018

No T cell activation in the absence of tumor



Cytokine release from PBMCs +/- drug and neuroblastoma cells IMR-32
Xu H et al. Cancer Immunol Res 2015;3:266-277



Y-mAbs 402 clinical trial

Changes when compared to FIH approach

Y-mAbs has chosen to change dose route and dosing strategy

- 1) Route of administration changed to s.c. known to reduce CRS slower onboarding Cmax estimated to be on day 2-5.
- 2) Dose frequency; based on MSKCC study limited to 2 doses per cycle. Based on KOL discussions:
 - Cycle length 2 weeks
 - Cycle 1 (week 1-2); dose day 1 and 8
 - Cycle 2-13 (week 3 to 26) dose day 1
- Cycle 14 to x (Week 27-EOT): x1 monthly (on day 1 every 2nd cycle)
- 3) Premedication: to include methyl prednisolone/ dexamethasone (or equivalent)
- 100 mg before dose 1 and 2; 50 mg: dose 3, 25 mg: dose 4 and thereafter p.n.



GD2xCD3 Biclone (Nivatrotamab) for development in SCLC

In total – 6 sites to be involved in the study

- Three sites identified, PI acceptance
 - Emory University School of Medicine Dr Owonikoko,
 - Fox chase cancer center Dr. Borghaei,
 - Washington University Dr. Morgenstern.
- Y-mAbs IND submission planned for December 2020 First patients enrolled Q1/Q2 2021

Patient Population 402

- The patient population for phase 1 of the trial will consist of <u>primary metastatic</u> (stage 4) or <u>relapsed</u> patients with SCLC regardless of platinum sensitivity. Patients will be eligible after failing the first-line platinum-containing treatment or after progressing on both second- and third-line treatments
- In phase 2, same patient population, and patients will be stratified into 2 groups based on whether they have <u>platinum sensitive</u> or <u>resistant disease</u>. Platinum sensitive disease is defined as platinum-free interval of ≥90 days and platinum resistant disease as platinum-free interval of ≤90 days.

