
**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): **March 12, 2019**

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.)

230 Park Avenue
Suite 3350
New York, New York 10169
(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))

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 x

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. x

ITEM 7.01 Regulation FD Disclosure

Y-mAbs Therapeutics, Inc., (the “Company”) is furnishing the company presentation attached as Exhibit 99.1 to this report for use at Cowen’s 39th Annual Health Care Conference in Boston, Massachusetts on March 12, 2019 and in other meetings with investors and analysts.

The Company’s updated corporate presentation has been posted to the Company’s website, www.ymabs.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information furnished pursuant to Item 7.01 on this Form 8-K 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 the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, the Company makes no admission as to the materiality of Item 7.01 in this report or the presentation available on the Company’s website. The information contained in the presentation is summary information that is intended to be considered in the context of the Company’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating its website or through other public disclosure.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Company Presentation, March 2019

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.

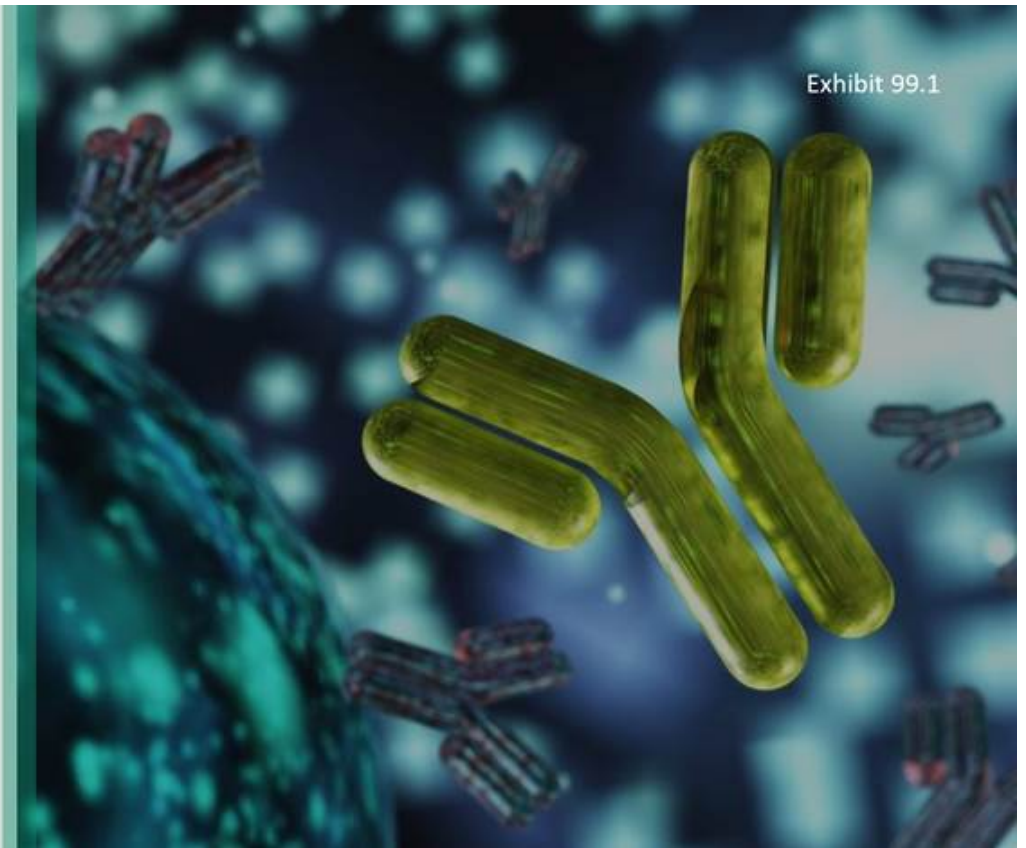
Date: March 12, 2019

By: /s/ Thomas Gad
Thomas Gad
Founder, Chairman, President and Head of Business Development



Company Presentation

March 2019



Disclaimer

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" 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 regulatory approvals, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, 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 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; our inability to enter into collaboration or alliances with partners; risks associated with protection of our intellectual property rights; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Registration Statement on Form S-1 declared effective by the SEC on 20 September, 2018 and in the Company's other SEC filings. 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.

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.

Our Mission

Our mission is to become the world leader in developing better and safer antibody-based pediatric oncology products addressing clear unmet medical needs

Investment Highlights



Two pivotal-stage candidates - naxitamab and omburtamab - with Breakthrough Therapy Designation

Late-stage, de-risked programs: 2 potential BLA submissions in 2019 - Plan for US commercialization, if approved

Potential to expand into other indications – studies ongoing

First Differentiated BsAb product candidate in Phase I/II

Worldwide rights to our current product candidates

Broad and Advanced Clinical Product Pipeline

Study	Indication/Treatment	Pre-clinical	Phase 1	Phase 2	Phase 3/ Registration	Next Milestone
Naxitamab GD2						
201	Relapsed/Refractory High-Risk Neuroblastoma (Pediatric)		Ongoing pivotal Phase 2 trial			2019-BLA Submission
12-230	Relapsed/Refractory High-Risk Neuroblastoma (Pediatric)		Ongoing Phase 2 trial			
16-1643	Front-Line High-Risk Neuroblastoma (Pediatric)		Ongoing Phase 2 trial			
15-096	Relapsed Second-Line Osteosarcoma		Ongoing Phase 2 trial			
17-251	Chemoimmunotherapy for Relapsed/Refractory High-Risk Neuroblastoma		Ongoing Phase 1 trial			
Omburtamab B7-H3						
101	CNS/Leptomeningeal Metastases from Neuroblastoma (Pediatric) (¹³¹ I)		Ongoing pivotal Phase 2 trial			2019-BLA Submission
03-133	Intrathecal Immunotherapy for CNS/Leptomeningeal Metastases (¹³¹ I)		Ongoing Phase 1 trial			
11-011	Diffuse Intrinsic Pontine Glioma (Pediatric) (¹²⁴ I)		Ongoing Phase 1 trial			
09-090	Desmoplastic Small Round Cell Tumor (Pediatric) (¹³¹ I)		Ongoing Phase 1 trial			
huGD2-BsAb GD2xCD3						
18-034	Refractory GD2-Positive Solid Tumors		Ongoing Phase 1 trial			

Broad Preclinical and Research Pipeline

Product Candidate	Target	Indication/Treatment	Next Anticipated Milestone
Omburtamab-DTPA	B7-H3	B7-H3 Positive CNS/Leptomeningeal Solid Tumors	IND 2019
huCD33-BsAb	CD33xCD3	Hematological Cancers Expressing CD33	IND 2020

Plus a bi-valent **ganglioside-based neuroblastoma vaccine candidate** and a number of non-disclosed BsAb constructs

Recent Achievements and Upcoming Milestones

2017	2018	2019
Recent Achievements		Upcoming Milestones
<ul style="list-style-type: none">✓ Achieved 3 RPDDs and 5 ODDs (3 FDA and 2 EMA)✓ Omburtamab granted BTM by the FDA in May 2017✓ Naxitamab granted BTM by the FDA in August 2018✓ Closed \$110mm IPO in September 2018✓ First bispecific IND approved in December 2018		<ul style="list-style-type: none"><input type="checkbox"/> Naxitamab R/R High-Risk NB BLA submission<input type="checkbox"/> Omburtamab CNS/LM from NB BLA submission<input type="checkbox"/> Omburtamab-DTPA IND Filing

Commercial Opportunity: De-Risked Base Case Plus Upside

Initial Commercial Opportunity	Candidate	Indication	Patient Population			Anticipated Annual Addressable Cases	Existing Competition
			U.S.	EU	Total		
Naxitamab		High-Risk R/R NB	700	1,050	1,750	~675	✗
		Relapsed Osteosarcoma	1,000	1,500	2,500	~300	✗
		Frontline NB	700	1,050	1,750	~960	✓ (1)
Omburtamab		CNS/LM from NB	700	1,050	1,750	~200	✗
		DIPG	300	450	750	~750	✗
		DSRCT	100	150	250	~160	✗



B7-H3+ CNS/LM from Solid Tumors 30,000 Patients in US and Europe combined



GD2+ Adult Solid Tumors >200,000 U.S. Patients

Significant Commercialization Advantages



Powerful partnership with leading treatment center



Memorial Sloan Kettering Cancer Center

Small number of treatment centers

Very small sales infrastructure

(1) Limitations of dinutuximab are longer infusion times (10-20 hours vs. 30 minutes), more frequent dosing and severe pain as the most common side effect.

Naxitamab: Anti-GD2 Antibody

Neuroblastoma and Osteosarcoma

Pivotal Stage Candidate: Naxitamab (Targets GD2)

Clinical	Regulatory	Commercial
In development for R/R high-risk NB	Studies 12-230 and 201 to form basis of BLA submission, expected in 2019:	No FDA approved therapies for R/R high risk NB
Study 12-230: Achieved ORR of 57% in 23 pediatric patients in Phase 1 and 53% ORR in 38 patients in Phase 2	Pending comparability, data from 12-230 and 201 may be pooled	Modest toxicity vs. other GD2 targeting antibodies
Study 201: Single-arm multi-center study using cGMP manufactured naxitamab; expected to enroll 37 patients	May qualify for accelerated approval if 30% ORR with minimum 12-week DoR	Shorter infusion time of ~30 minutes in an outpatient setting vs. 10-20 hours with hospitalization of several days for others; may decrease need for pain medication
Administered to >200 patients to date	Orphan Drug, Breakthrough Therapy and Rare Pediatric Disease Designation ⁽¹⁾	Plan for US commercialization, if approved

Also being evaluated in (i) a Phase 2 study in front-line (Study 16-1643), (ii) in a Phase 1 pilot combo study with chemo (17-251) for refractory NB patients with soft tissue disease, and (iii) with GM-CSF in a Phase 2 study (15-096) in 2nd line relapse osteosarcoma

(1) Indicates eligibility for a Priority Review Voucher, or PRV, on approval.

Naxitamab: Clinical Overview – Study 12-230 Results

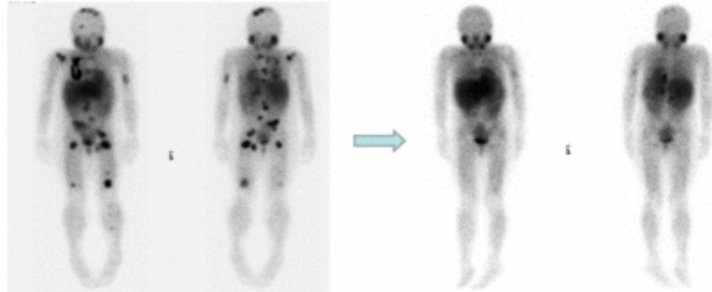
Phase 1 (Dose escalation)

Patients and Efficacy	
Patient group	CR/PR
Primary refractory (n = 11)	8 (73%)
Secondary refractory (n = 12)	5 (42%)
All patients with non-PD (n = 23)	13 (57%)

Phase 2 (Fixed dose – 9mg/kg per week)

Patients and Efficacy	
Patient group	CR/PR
Primary Refractory response rate: (n=15)	13 (87%)
Secondary Refractory response rate: (n=23)	7 (30%)
Results (Through January 2018) – (n =38)	20 (53%)

¹²³I-MIBG scans before and after naxitamab and GM-CSF treatment ⁽¹⁾



(1) Although not every patient will experience similar results, we believe these scans are indicative of a patient that has responded favorably to naxitamab and GM-CSF treatment.

Naxitamab: Key Takeaways

Our Lead Candidate Addresses Significant Unmet Needs in R/R High-Risk NB and has the Potential to Expand its Application to Broader Populations

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

Naxitamab has been granted BTM, RPDD⁽¹⁾, and ODD

Study 12-230 and Study 201 to form primary basis of BLA submission

Potential to expand application to the treatment of adults with cancers that express GD2

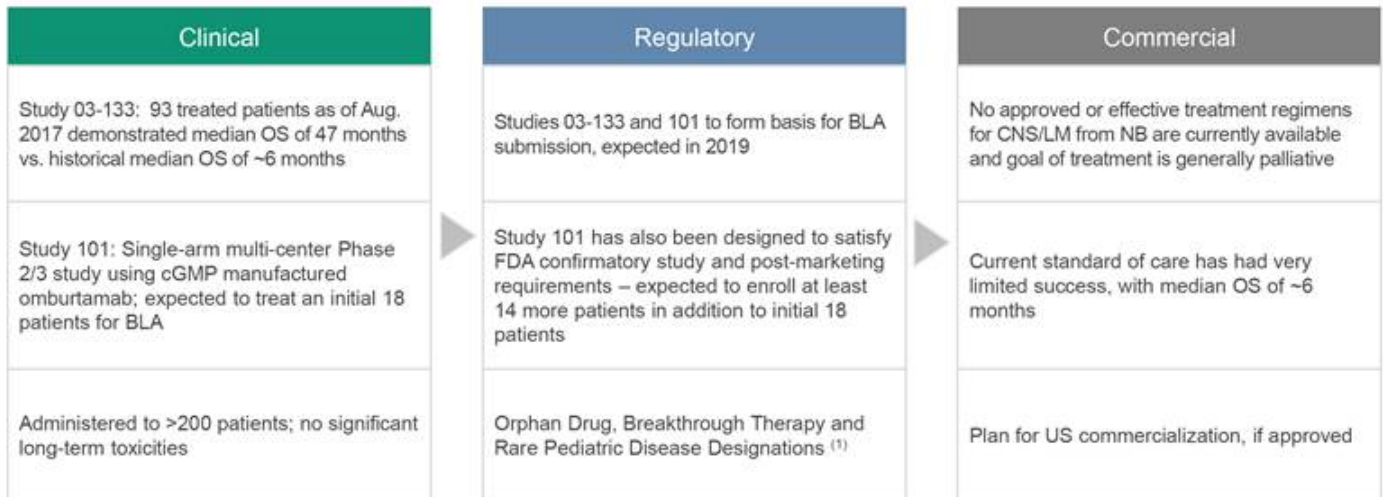
BLA submission expected in 2019, US commercialization being planned by Y-mAbs

(1) Indicates eligibility for a Priority Review Voucher, or PRV, on approval.

Omburtamab – B7-H3 Targeting Antibody

CNS/LM from NB, DIPG and DSRCT

Pivotal Stage Lead Product Candidate: Omburtamab (Targets B7-H3)

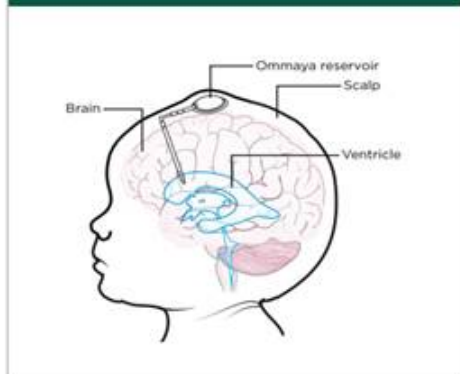


(1) Indicates eligibility for a Priority Review Voucher, or PRV, on approval

Omburtamab: Clinical Overview

CNS/LM from NB patients

Administration of radiolabeled omburtamab via Ommaya reservoir



Omburtamab being delivered in an outpatient setting



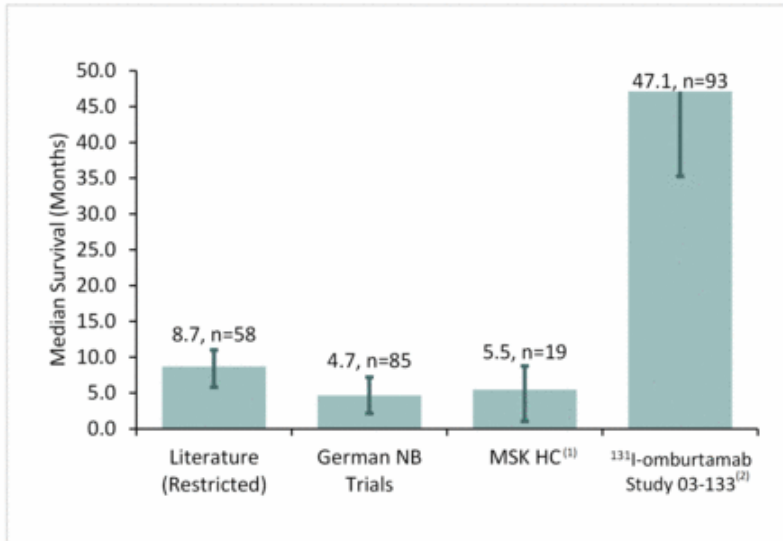
PET scan of distribution of radiolabeled omburtamab two hours after administration



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: ¹³¹I-Omburtamab Improves Survival in CNS/LM from NB Patients



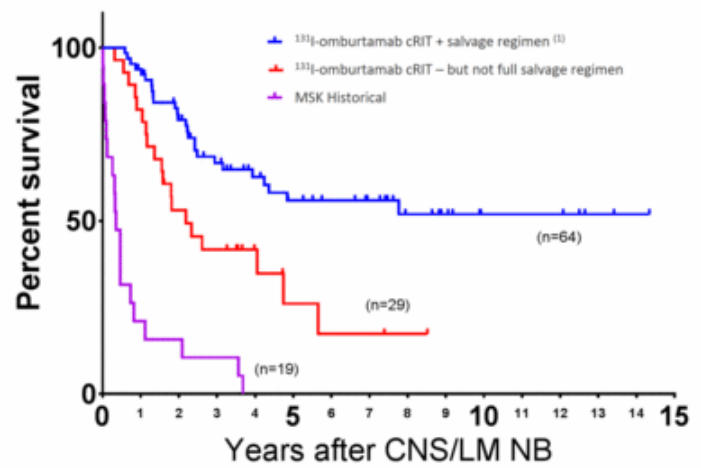
These results further demonstrate the lack of an established, effective therapy for patients with CNS/LM from NB that we believe can potentially be addressed by ¹³¹I-omburtamab

(1) MSK HC = neuroblastoma patients with CNS/LM treated at MSK prior to 2003.
(2) ¹³¹I-omburtamab = Patients with CNS/LM treated under Study 03-133.

Omburtamab: Clinical Overview

CNS/LM from NB patients – MSK Historical vs ^{131}I -omburtamab

Treated Patients Receiving Salvage Treatment Showed a Marked Improvement in Survival



(1) Salvage regimen (Kramer et al. J Neurooncology 97:409, 2012)

Omburtamab: Key Takeaways

Our Lead Candidate 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 or, as widely accepted, no effective treatment regimens; goal of treatment is generally palliative

Demonstrated median OS of 47 months (including an estimated five-year OS of ~43%), as compared to historical median OS of ~six months and no expected five-year survival

Granted BTDD, RPDD⁽¹⁾, and ODD

We believe there is a large market opportunity for the treatment of solid tumors that express B7-H3

Study 03-133 together with Study 101 to form primary basis for BLA submission

BLA for treatment of patients with CNS/LM from NB expected to be submitted in 2019. May qualify for a sBLA for DIPG and DSRCT assuming positive pivotal data

⁽¹⁾ Indicates eligibility for a Priority Review Voucher, or PRV, on approval.

^{177}Lu -omburtamab-DTPA: B7-H3 Targeting Antibody

Targeting B7-H3 Positive Solid Tumors



Omburtamab: Exploring Additional Cancer Indications

Study 03-133 - Patient Profile (Jan 2004 – Aug 2017)

Cancer Diagnosis	No. of Patients	No. Of Injections
Neuroblastoma	93	293
Medulloblastoma / PNET	15	29
Ependymoma	9	37
EMTR	2	4
Sarcoma	6	18
Melanoma	4	9
Other(*)	5	22
Total	134	412

Update on data from others cancers expected in 2019

* Includes ATRT, choroid plexus cancer, ovarian cancer, retinoblastoma.

¹⁷⁷Lu-omburtamab-DTPA Pediatric and Adult Strategy

Pediatric

First indication: **Medulloblastoma**

Prior experience from compartmental treatment with ¹³¹I radiolabeled GD2 and B7-H3 antibodies

Dose of 2x 50mCi ¹³¹I radiolabeled omburtamab

Adult

First indication: **Basket Trial** of B7-H3 positive CNS/LM tumors

Prior experience from compartmental treatment of adult patients with ¹³¹I radiolabeled omburtamab

Dose of 2x 50mCi ¹³¹I radiolabeled omburtamab

Clinical Testing

Clinical experience using ¹³¹I-omburtamab in 41 patients with tumors such as sarcoma, melanoma and medulloblastoma

Animal toxicity studies of **omburtamab-DTPA** completed on GLP material

cGMP production established

Expect to file an IND for treatment of B7-H3 positive LM from solid tumors in 2019

Bispecific Antibodies

First Two Antibodies Targeting GD2 and CD33 Positive Cancers

Bispecific Antibody Platform

huGD2-BsAb and huCD33-BsAb

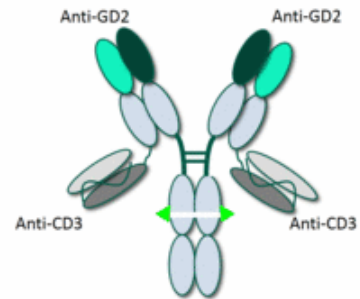
huGD2-BsAb – GD2 Positive Solid Tumors – Clinical Phase I/II study ongoing

Potential Advantages Over Other BsAbs

- Improved potency due to bivalency towards GD2, while maintaining functional monovalency towards CD3
- Longer serum half-life to improve efficacy and patient convenience
 - Molecular size of 210kD (vs. 55kD size of blinatumomab)
 - Binding to neonatal Fc receptor result in longer serum half-life, thereby reducing the need for continuous infusion
- Better safety profile
 - The larger molecule size prevents leakage into the CNS thereby avoiding CNS neurotoxicity;
 - Low affinity for CD3 molecules and functional monovalency towards CD3 reduces risk of significant cytokine release; and
 - Lower immunogenicity as shown by the low immunogenicity profile of naxitamab

Refractory GD2+ Solid Tumors – Incidence >200,000 per year in the U.S.

Structure



huCD33-BsAb – Hematological Malignancies Expressing CD33

huCD33-BsAb is a humanized anti-CD33 and anti-CD3 BsAb

Potential IND submission in 2020

Bispecific GD2 Antibody Candidate

Currently in Phase 1/2 Clinical Development



Phase 1/2 clinical trial initiated. Recruiting patients with:

Relapsed/refractory neuroblastoma;

High grade osteosarcoma;

Other GD2(+) solid tumors, where patients have relapsed or refractory disease that is resistant to standard therapy.

30 patients across two cohorts (RR Neuroblastoma, RR Osteosarcoma)

Phase 1 endpoints

Maximum tolerated dose, recommended phase 2 dose, PK, HABA, anti-tumor, overall survival

Phase 2 endpoints

RR Neuroblastoma: overall survival, duration of complete remission

RR Osteosarcoma: progress-free survival at four months

Overall survival

Commercial Summary

Commercial Production

cGMP Production for:

Naxitamab

Drug Substance - Up and Downstream manufacturing:

Groningen, NL

ThermoFisher
SCIENTIFIC

Drug Product - Fill and Finish:

Greenville North Carolina, US

Omburtamab

Drug Substance - Up and Downstream manufacturing:

Martillac, France

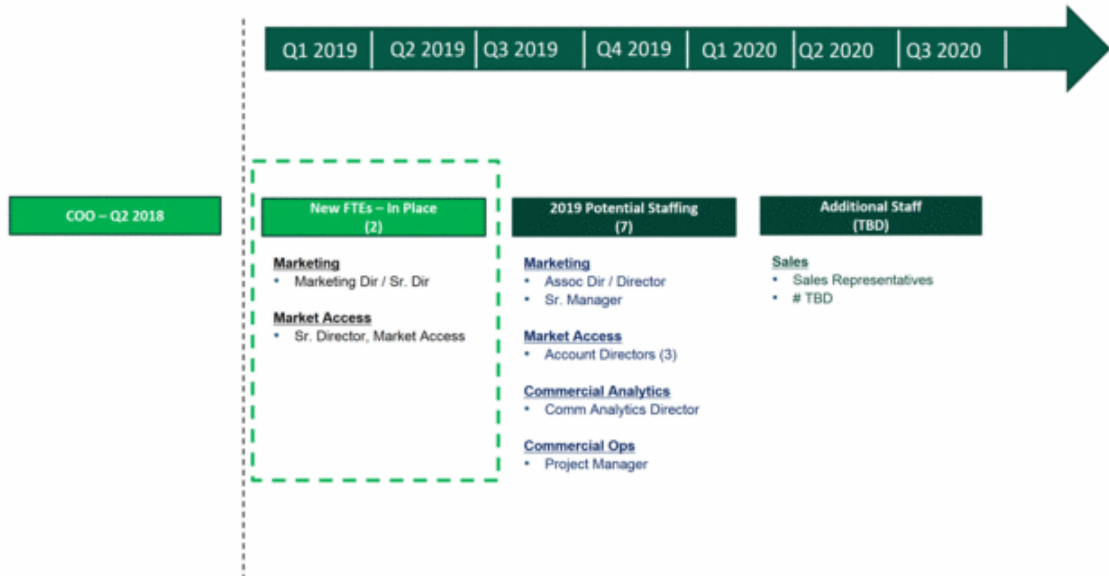
Merck KGaA
Darmstadt, Germany

Drug Product - Fill and Finish:

Ferentino, Italy

ThermoFisher
SCIENTIFIC

Commercials Resourcing US



Financial Summary

Strong Financial Position with Blue Chip Investors

Y-mAbs Has Completed a Series of Successful Financing Rounds, with \$230 million Raised to Date



\$163.3 million of cash and cash equivalents as of September 30, 2018

Investment Highlights



Two pivotal-stage candidates - naxitamab and omburtamab - with Breakthrough Therapy Designation

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First Differentiated BsAb product candidate in Phase I/II

Worldwide rights to our current product candidates

