Y-mAbs Announces Second Quarter 2019 Financial Results and Recent Corporate Developments

August 14, 2019

NEW YORK, Aug. 14, 2019 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today reported financial results for the second quarter of 2019.

"We are very pleased with our second quarter results, highlighted by prudent spending combined with notable progress in the preparation of the initial portions of our rolling BLAs for our two lead product candidates, naxitamab and omburtamab, for submission to the FDA later this year. We continue to solidify our position as a leader in pediatric oncology and as a company focused on rapidly developing therapies to extend and enhance the lives of those living with rare pediatric cancers," stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, "We believe our recent pre-BLA meeting with the FDA supports our ambition of initiating submission of a rolling BLA for naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma in the fourth quarter of 2019, with the expectation that the final portion will be submitted in early 2020. We are also excited to initiate the submission of a rolling BLA for omburtamab for the treatment of central nervous system/leptomeningeal metastasis from neuroblastoma by the end of 2019, and expect to submit the two rolling BLAs almost concurrently. These are exciting times for Y-mAbs."

Second Quarter 2019 and Recent Corporate Developments

- Subsequent to the end of the second quarter, on July 8, 2019, Y-mAbs announced that it has completed a successful pre-BLA meeting with the FDA regarding a potential pathway for FDA approval of naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma. During the meeting, the Company reached alignment with the FDA on an Accelerated Approval Pathway for naxitamab along with a rolling BLA submission. The Company expects to submit the Clinical/Safety portion and the non-Clinical portion of the BLA in November 2019. For the Chemistry, Manufacturing and Controls (CMC) portion, the Company believes it will have sufficient data from the Process Performance Qualification (PPQ) batches to complete the CMC portion in early 2020. Y-mAbs continues to evaluate potential avenues to accelerate the submission of the CMC portion, and hopes to comply with FDA requirements at an earlier time.

- Also subsequent to the end of the second quarter, on July 1, 2019, Y-mAbs announced the status of patient recruitment for the Company's two pivotal phase II trials, one for omburtamab for the treatment of central nervous system/leptomeningeal metastasis (CNS/LM) from neuroblastoma and the other for naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma. As of June 30, 2019, all of the 18 planned omburtamab patients had been enrolled in the study. The Company believes it remains on track to start submission of a rolling BLA in 2019 under the Breakthrough Therapy Designation that the Company previously received from the FDA. For naxitamab, more than 30 patients of a planned total of 37 patients in the Company's Study 201 had been enrolled in the study as of June 30, 2019.

- After the close of the second quarter, on July 1, 2019, Y-mAbs announced that the Company has entered into a development, manufacturing and supply agreement with SpectronRx in South Bend, Indiana, to secure access to clinical and commercial scale radiolabeling capacity for omburtamab. Under the terms of the agreement, SpectronRx has agreed to establish a manufacturing unit designated for Y-mAbs within its existing facilities, at which Y-mAbs believes both clinical and commercial supply of radiolabeled omburtamab can be produced.

- On June 26, 2019, Y-mAbs announced the acceptance of two oral presentations and five poster presentations at the International Society of Pediatric Oncology (SIOP) Annual Congress for its two lead product candidates, naxitamab and omburtamab.

- On May 15, 2019, Y-mAbs announced the acceptance of three poster presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting for its two lead product candidates, naxitamab and omburtamab.

- On May 14, 2019, Y-mAbs announced an update on its GD2-GD3 Vaccine program for relapsed high-risk neuroblastoma. A total of 230 patients have received the GD2-GD3 Vaccine to date and Y-mAbs plans to begin using a newly manufactured Current Good Manufacturing Practice (cGMP) drug product in the fourth quarter of 2019.

Second Quarter 2019 Financial Results

Y-mAbs reported a net loss of $18.0 million, or $0.53 per basic and diluted share, for the three months ended June 30, 2019, compared to a net loss of $10.3 million, or $0.39 per basic and diluted share, for the three months ended June 30, 2018.

For the six months ended June 30, 2019, Y-mAbs reported a net loss of $34.0 million, or $0.99 per basic and diluted share, compared to a net loss of $17.8 million, or $0.66 per basic and diluted share, reported for the six months ended June 30, 2018.

Operating Expenses

Research and Development
Research and development expenses were $14.5 million for the three months ended June 30, 2019, compared to $8.3 million for the three months

ended June 30, 2018, an increase of $6.2 million. The increase in research and development expenses primarily reflects the following:

- $2.9 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab;
- $2.2 million increase in outsourced research and supplies to support expanding development activities; and
- $0.7 million increase in personnel costs.

Research and development expenses were $27.0 million for the six months ended June 30, 2019, compared to $14.5 million for the six months ended June 30, 2018, an increase of $12.5 million. The increase in research and development expenses primarily reflects the following:

- $7.2 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab;
- $3.5 million increase in outsourced research and supplies to support expanding development activities; and
- $1.4 million increase in personnel costs.

General and Administration
General and administrative expenses were $4.1 million for the three months ended June 30, 2019, compared to $2.0 million for the three months ended June 30, 2018, an increase of $2.1 million. Such increase in general and administrative expenses primarily reflects the following:

- $1.4 million increase in personnel costs; and
- $0.5 million increase in commercial infrastructure.

General and administrative expenses were $7.9 million for the six months ended June 30, 2019, compared to $3.2 million for the six months ended June 30, 2018, an increase of $4.7 million. Such increase in general and administrative expenses primarily reflects the following:

- $2.8 million increase in personnel costs; and
- $0.8 million increase in commercial infrastructure costs.

Cash and Cash Equivalents
The Company had approximately $120.2 million in cash and cash equivalents as of June 30, 2019, compared to $147.8 million as of December 31, 2018. The decrease of $27.6 million was primarily attributable to the increased costs of operation as the Company prepares for its submission of rolling BLAs for naxitamab and omburtamab and the build-up of the Company's commercial infrastructure.

Webcast and Conference Call

The Company will host a conference call today at 4:30 pm Eastern Time. To participate in the call, please dial (877) 407-0792 (domestic) or (201) 689-8263 (international) and reference the access code 13693605. A webcast will be available at: http://public.viavid.com/index.php?id=135790

About Y-mAbs

Y-mAbs is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The Company has a broad and advanced product pipeline, including two pivotal-stage product candidates —naxitamab and omburtamab—which target tumors that express GD2 and B7-H3, respectively.

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 The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about our business model and development and commercialization plans; current and future clinical and pre-clinical studies and our research and development programs; regulatory, marketing and reimbursement approvals; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements; developments relating to our competitors and our industry; and other statements that are not historical facts. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will", "would" 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 our financial condition and need for additional capital; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay or failure to receive approval of our drug candidates; the risks related to commercializing any approved 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; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock 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 and in our other SEC filings. 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.

Y-MABS THERAPEUTICS, INC.
Consolidated Balance Sheets
(unaudited)
(in thousands, except share data)

	June 30, 2019	December 31, 2018

ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$120,163	$147,840
Restricted cash	-	31
Other current assets	3,027	3,661
Total current assets	123,190	151,532
Property and equipment, net	390	205
Operating lease right-of-use lease assets	2,216	-
Other assets	244	187
TOTAL ASSETS	$126,040	$151,924
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$8,911	$5,872
Accrued liabilities	4,215	3,251
Lease obligations	502	-
Total current liabilities	13,628	9,123
Accrued milestone and royalty payments	2,050	2,050
Lease obligations	1,980	-
Other liabilities	-	224
TOTAL LIABILITIES	17,658	11,397
STOCKHOLDERS' EQUITY		
Preferred stock $0.0001 par value, 5,500,000 shares authorized at June 30, 2019 and December 31, 2018; none issued at June 30, 2019 and December 31, 2018	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2019 and December 31, 2018; 34,193,666 shares issued at June 30, 2019 and December 31, 2018	3	3
Additional paid in capital	227,187	225,352
Accumulated other comprehensive income/(loss)	(3)	7
Accumulated deficit	(118,805)	(84,835)
TOTAL STOCKHOLDERS' EQUITY	108,382	140,527
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$126,040	$151,924

Y-MABS THERAPEUTICS, INC.
Consolidated Statements of Comprehensive Loss
(unaudited)
(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
OPERATING EXPENSES				
Research and development	$14,494	$8,293	$27,005	$14,497
General and administrative	$4,140	$1,965	$7,882	$3,240
Total operating expenses	18,634	10,258	34,887	17,737
Loss from operations	(18,634)	(10,258)	(34,887)	(17,737)

OTHER INCOME/(EXPENSES)				
Other income/(expenses)	598	(47)	917	(51)
NET LOSS	($18,036)	($10,305)	($33,970)	($17,788)
Other comprehensive income/(loss)				
Foreign currency translation	(66)	78	(10)	81
COMPREHENSIVE LOSS	($18,102)	($10,227)	($33,980)	($17,707)
Net loss per share attributable to common stockholders, basic and diluted	($0.53)	($0.39)	($0.99)	($0.66)
Weighted average common shares outstanding, basic and diluted	34,193,666	26,749,666	34,193,666	26,749,666

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