I-Mab Reports Financial Results for the Six Months Ended June 30 and Provides Corporate Update

8月 31, 2020

Positive preliminary clinical trial results for lemzoparlimab (TJC4) demonstrate a differentiated drug profile in safety and pharmacokinetics in cancer patients

Joined the global effort against COVID-19 with plonmarlimab (TJM2) study which represents the first double-blind, placebo-controlled study evaluating anti-GM-CSF antibody in severe COVID-19 patients

The Company expects significant pipeline updates in H2 2020 including China registrational trial with CD38 antibody felzartamab (TJ202) as third-line monotherapy for multiple myeloma; the Company also expects IND approval for eftansomatropin (TJ101), a unique long acting growth hormone in the fourth quarter of 2020 and to initiate phase 3 study subsequently

The Company to host conference call and webcast on August 31 at 8:00 a.m. ET

SHANGHAI and GAITHERSBURG, Md., Aug. 31, 2020 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced financial results for the six months ended June 30, 2020 and provided an overview of recent highlights and upcoming milestones.

"I-Mab continues to advance our robust pipeline, create value through innovation, and is well positioned to become a fully integrated global biopharmaceutical company. The differentiation of our innovative assets has become validated as the clinical trials progress, as exemplified by our positive preliminary clinical results for lemzoparlimab," said Dr. Jingwu Zang, Founder, Honorary Chairman and Director of I-Mab. "Looking ahead, we remain excited and confident in our science and increasing capabilities to deliver the promised corporate and pipeline development milestones and create value for patients as well as for our shareholders."

The Company expects multiple data readouts across a progressing pipeline in the coming months. These include the clinical results of phase 1 clinical trial in the U.S. and China for lemzoparlimab, initial data from uliledlimab (TJD5), the differentiated CD73 antibody, Part 2 clinical update from plonmarlimab in patients with cytokine release syndrome associated with severe COVID-19, as well as phase 2 results from olamkicept (TJ301) in patients with ulcerative colitis. Felzartamab (TJ202), the Company's in-licensed CD38 antibody, is being evaluated in two parallel registrational studies in China for the treatment of multiple myeloma and is on track for subject enrollment.

In addition, the Company's recent appointment of Chief Commercial Officer Ivan Yifei Zhu marks the Company's commitment to building commercial capability and executing our commercialization plans for upcoming product launches. The remarkable progress in pipeline and corporate development demonstrated during this period significantly strengthens the Company's position to achieve longer-term growth into 2021 and beyond.

Recent Highlights and Upcoming Milestones

Internally Discovered Global Pipeline

- TJC4 or lemzoparlimab (differentiated anti-CD47):
  - *Clinical development in the U.S.:* Lemzoparlimab is one of the leading drug candidates among I-Mab's proprietary and innovative pipeline. It is designed to minimize inherent binding to normal red blood cells while preserving its strong anti-tumor activity, a critical attribute in differentiating lemzoparlimab from some other antibodies of the same class currently in development. The topline results of the recently completed phase 1 dose-escalation clinical trial in the U.S. have demonstrated the differentiated profile of lemzoparlimab in drug safety and favorable pharmacokinetics in cancer patients. The results have shown that lemzoparlimab is well tolerated as a single agent at a dose range of up to 30 mg/kg without introducing any priming dosing strategy. In all DLT-evaluable patients, no dose-limiting toxicities or severe hematologic adverse events were observed. Detailed data will be released separately and presented at an appropriate scientific conference later this year. The on-going U.S. study has proceeded into a combination trial with PD-1 inhibitor pembrolizumab (KEYTRUDA®) in cancer patients with several types of solid tumors through a collaboration with Merck Sharp & Dohme Corp (MSD) and Rituximab (RITUXAN®) in patients with Non-Hodgkin's lymphoma (NHL).
  - *Clinical development in China:* Lemzoparlimab is being evaluated in a Phase 1/2a clinical trial in patients with relapsed or refractory acute myeloid leukemia (r/r AML) or myelodysplastic syndrome (MDS) in China. Results are expected in early 2021.

- TJD5 or uliledlimab (differentiated anti-CD73):

- *Clinical development in the U.S.:* TJD5 is being evaluated in a Phase 1, dose-escalation clinical trial to examine the safety, tolerability and preliminary efficacy of the combination therapy with atezolizumab (in collaboration with Roche) in patients with advanced solid tumors. The preliminary data are expected in the fourth quarter of 2020.
- *Clinical development in China:* TJD5 is on track in a Phase 1 clinical trial to evaluate the safety, tolerability, PK/PD, and potential efficacy primarily in patients with solid tumors, including lung cancer, as a single agent and the combination therapy with a PD-1 (in collaboration with Junshi).

- TJM2 or plonmarlimab (anti-GM-CSF):
  - In May 2020, I-Mab announced results from Part 1 of a multi-center, double blinded, randomized, placebo-controlled, three-arm clinical study of TJM2 in patients with cytokine release syndrome (CRS) associated with severe COVID-19. TJM2 is found to be well tolerated in patients with severe COVID-19.
  - I-Mab is currently conducting Part 2 of the clinical trial to evaluate the efficacy, safety and cytokine levels following a single dose of 6 mg/kg TJM2 or placebo (standard care) in patients with severe COVID-19. The Company is currently in discussion with the FDA to finalize the plan for TJM2 in relation to clinical development and potential registration in the U.S.
  - I-Mab has recently initiated a multiple-dose Phase 1b study with TJM2 in patients with rheumatoid arthritis (RA) in China.

- Early-stage pipeline of novel monoclonal antibodies advancing toward clinical development in the U.S. and China:
  - TJ210 is a novel monoclonal antibody directed at C5aR for cancers through a partnership with MorphoSys. I-Mab submitted IND to the U.S. FDA in August and plan to subsequently initiate clinical development in the U.S. upon IND approval. I-Mab also plans to initiate development of TJ210 in China.
  - In June 2020, I-Mab and ABL Bio presented preclinical data on a newly developed, novel bispecific antibody, TJ-CD4B, at the American Association for Cancer Research (AACR) Virtual Annual Meeting. TJ-CD4B has a duel targeting property combining Claudin 18.2 (a gastric- and pancreatic-specific cancer antigen) and 4-1BB and is uniquely structured to supercharge T cells in a Claudin 18.2-dependent manner, enhancing anti-tumor immunity while potentially minimizing toxicity.

"Fast to Market" China Portfolio

- TJ202 or felzartamab (differentiated anti-CD38) for multiple myeloma (MM):
  - I-Mab is conducting two parallel registrational trials with TJ202 as a third-line monotherapy and as a second line combination therapy with lenalidomide, both in patients with multiple myeloma in Taiwan and mainland China. The trials are ongoing, and recruitment progress remains on track. The Company expects to complete a BLA submission in 2021.

- TJ101 or eftansomatropin (differentiated long-acting growth hormone) for pediatric growth hormone deficiency (PGHD):
  - The China National Medical Products Administration (NMPA) has accepted an IND application for a registrational phase 3 study to assess the efficacy, safety and pharmacokinetics of TJ101 in PGHD. The Company expects to obtain IND approval in the fourth quarter of 2020 and initiate the phase 3 study subsequently.

- TJ107 or efineptakin alfa (long-acting interleukin 7) for glioblastoma multiforme (GBM):
  - Following a phase 1b clinical trial, I-Mab has obtained regulatory clearance from the China NMPA to initiate a phase 2 clinical trial with TJ107 in glioblastoma multiforme patients with lymphopenia in the fourth quarter of 2020.

- TJ301 or olamkicept (differentiated interleukin-6 inhibitor) for ulcerative colitis (UC) and other autoimmune diseases:
  - The phase 2 clinical trial is on-going to enroll remaining patients to assess the pharmacokinetics, safety, and efficacy of TJ301 in patients with active ulcerative colitis. The enrollment is expected to complete in the third quarter of 2020. Topline data is expected to be released by early 2021.

Corporate

- In July 2020, I-Mab's Board of Directors authorized a stock repurchase program under which the Company may repurchase up to US$20 million of its ordinary shares in the form of American depositary shares.

- In July 2020, I-Mab announced its 2020 Share Incentive Plan (the "Plan"), the maximum aggregate number of shares which may be issued pursuant to all awards shall be 10,760,513 Ordinary Shares. The purpose of the Plan is to provide management and staff with ownership-based incentives for achievements of critical corporate and clinical development milestones to generate superior returns to the Company's shareholders.

- In May 2020, I-Mab expanded its global footprint with the opening of the Company's Hong Kong office, serving as a regional hub for the Company's capital markets and investor relations activities.

Commercialization Capability

- In July 2020, I-Mab appointed Mr. Ivan Yifei Zhu as the Company's Chief Commercial Officer. Mr. Zhu has more than 20 years of successful commercialization experience and held senior executive positions at global, domestic pharma and biotech companies. In his new role, Mr. Zhu will focus on building and developing I-Mab's commercialization infrastructure and strategies and preparing the Company for upcoming product launches.

First Half 2020 Financial Results

Cash Position

As of June 30, 2020, the Company had cash, cash equivalents, restricted cash and short-term investments of RMB1.6 billion (US$221.1 million), compared with RMB1.2 billion as of December 31, 2019.

Net Revenues

Total net revenues for the six months ended June 30, 2020 were nil, compared with RMB15.0 million for the six months ended June 30, 2019.

Research & Development Expenses

Research and development expenses for the six months ended June 30, 2020 were RMB442.3 million (US$62.6 million), compared with RMB265.1 million for the six months ended June 30, 2019. The increase was primarily due to increases in CRO service fees to advance the Company's pipelines, higher share-based compensation, and higher employee salary and benefits expenses due to increased research and development headcount.

Administrative Expenses

Administrative expenses for the six months ended June 30, 2020 were RMB171.4 million (US$24.3 million), compared with RMB574.6 million for the six months ended June 30, 2019. The decrease was primarily due to reduced share-based compensation expenses of RMB268.9 million (US$38.1 million).

Net Loss

Net loss for the six months ended June 30, 2020 was RMB582.9 million (US$82.5 million), compared with RMB857.3 million for the six months ended June 30, 2019. Net loss per share attributable to ordinary shareholders for the six months ended June 30, 2020 was RMB4.78 (US$0.68), compared with RMB119.34 for the six months ended June 30, 2019.

Non-GAAP Net Loss

Non-GAAP adjusted net loss, which excludes share-based compensation expenses, for the six months ended June 30, 2020 was RMB353.1 million (US$50.0 million), compared with RMB491.0 million for the six months ended June 30, 2019. Non-GAAP adjusted net loss per share attributable to ordinary shareholders for the six months ended June 30, 2020 was RMB2.90 (US$0.41), compared with RMB68.34 for the six months ended June 30, 2019.

Conference Call and Webcast Information

The Company will host a live conference call and webcast on August 31, 2020 at 8:00 a.m. ET. Participants **must register in advance** of the conference call. Details are as follows:

Registration Link:http://apac.directeventreg.com/registration/event/8959387
Conference ID: 8959387

Upon registering, each participant will receive a dial-in number, Direct Event passcode, and a unique access PIN, which can be used to join the conference call.

A webcast replay will be archived on the Company's website for one year after the conclusion of the call at http://ir.i-mabbiopharma.com.

A telephone replay will be available approximately two hours after the conclusion of the call. To access the replay, please call +1-855-452-5696 (U.S.), +61-2-8199-0299 (International), 400-632-2162 (Mainland China), or 800-963-117 (Hong Kong). The conference ID number for the replay is 8959387.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-PoC (Proof-of-Concept) and Fast-to-Market development strategies through internal R&D and global partnerships. The Company is on track to transitioning from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facility and commercial capability. I-Mab has offices in Beijing, Shanghai, Hong Kong and Maryland, United States. For more information, please visit http://ir.i-mabbiopharma.com

Use of Non-GAAP Financial Measures

To supplement its consolidated financial statements which are presented in accordance with U.S. GAAP, the Company uses adjusted net loss as a non-GAAP financial measure. Adjusted net loss represents net loss before share-based compensation. The Company's management believes that adjusted net loss facilitates better understanding of operating results and provide management with a better capability to plan and forecast future periods. For more information on the non-GAAP financial measures, please see the table captioned "Reconciliation of GAAP and Non-GAAP Results" set forth at the end of this press release.

Non-GAAP information is not prepared in accordance with GAAP and may be different from non-GAAP methods of accounting and reporting used by

other companies. The presentation of this additional information should not be considered a substitute for GAAP results. A limitation of using adjusted net loss is that adjusted net loss excludes share-based compensation expense that has been and may continue to be incurred in the future.

Exchange Rate Information

This announcement contains translations of certain RMB amounts into U.S. dollars at a specified rate solely for the convenience of the reader. Unless otherwise noted, all translations from Renminbi to U.S. dollars are made at a rate of RMB7.0651 to US$1.00, the rate in effect as of June 30, 2020 published by the Federal Reserve Board.

Safe Harbor Statement

This press release contains statements that may constitute "forward-looking" statements pursuant to the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "aims," "future," "intends," "plans," "believes," "estimates," "likely to" and similar statements. Statements that are not historical facts, including statements about I-Mab's beliefs, plans and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. Further information regarding these and other risks is included in I-Mab's filings with the SEC. All information provided in this press release is as of the date of this press release, and I-Mab does not undertake any obligation to update any forward-looking statement, except as required under applicable law.

For more information, please contact:

I-Mab
Jielun Zhu, CFO
E-mail: jielun.zhu@i-mabbiopharma.com
Office line: +86 21 6057 8000

Gigi Feng, Vice President and Global Head of Corporate Communications
E-mail: Gigi.Feng@i-mabbiopharma.com
Office line: +86 21 6057 8000

Investor Inquiries:
Burns McClellan, Inc. (Americas and Europe)
Steve Klass
E-mail: sklass@burnsmc.com
Office line: +1 212 213 0006

The Piacente Group, Inc. (Asia)
Emilie Wu
E-mail: emilie@thepiacentegroup.com
Office line: + 86 21 6039 8363

I-MAB
Consolidated Balance Sheets
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	As of December 31, 2019	As of June 30, 2020	
	RMB	RMB	US$
Assets			
Current assets			
Cash and cash equivalents	1,137,473	1,560,031	220,808
Restricted cash	55,810	-	-
Short-term investments	32,000	1,926	273
Prepayments and other receivables	136,036	131,130	18,560
Total current assets	1,361,319	1,693,087	239,641
Property, equipment and software	30,069	26,625	3,769
Operating lease right-of-use assets	16,435	17,592	2,490
Intangible assets	148,844	148,844	21,068
Goodwill	162,574	162,574	23,011
Other non-current assets	18,331	-	-
Total assets	**1,737,572**	**2,048,722**	**289,979**
Liabilities, mezzanine equity and shareholders' equity (deficit)			
Current liabilities			
Short-term borrowings	50,000	-	-
Accruals and other payables	273,553	243,068	34,404
Operating lease liabilities, current	6,807	8,202	1,161
Ordinary shares to be issued to Everest	258,119	-	-
Total current liabilities	588,479	251,270	35,565

Convertible promissory notes	68,199	69,138	9,787
Operating lease liabilities, non-current	7,492	7,254	1,027
Deferred subsidy income	3,920	7,760	1,098
Other non-current liabilities	-	9,424	1,334
Total liabilities	**668,090**	**344,846**	**48,811**
Mezzanine equity			
Series A convertible preferred shares (US$0.0001 par value, 30,227,056 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of June 30, 2020)	687,482	-	-
Series B convertible preferred shares (US$0.0001 par value, 30,305,212 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of June 30, 2020)	921,243	-	-
Series C convertible preferred shares (US$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of June 30, 2020)	1,306,633	-	-
Series C-1 convertible preferred shares (US$0.0001 par value, 3,857,143 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of June 30, 2020)	188,819	-	-
Total mezzanine equity	**3,104,177**	**-**	**-**

I-MAB
Consolidated Balance Sheets
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	As of December 31,	As of June 30,	
	2019	2020	
	RMB	RMB	US$
Shareholders' equity (deficit)			
Ordinary shares (US$0.0001 par value, 500,000,000 and 800,000,000 shares authorized as of December 31, 2019 and June 30, 2020, respectively; 8,363,719 and 133,006,644 shares issued and outstanding as of December 31, 2019 and June 30, 2020, respectively)	6	92	13
Additional paid-in capital	389,379	4,675,991	661,844
Accumulated other comprehensive income	70,127	104,853	14,841
Accumulated deficit	(2,494,207)	(3,077,060)	(435,530)
Total shareholders' equity (deficit)	**(2,034,695)**	**1,703,876**	**241,168**
Total liabilities, mezzanine equity and shareholders' equity (deficit)	**1,737,572**	**2,048,722**	**289,979**

I-MAB
Consolidated Statements of Comprehensive Loss
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the six months ended June 30,		
	2019	2020	
	RMB	RMB	US$
Revenues			
Licensing and collaboration revenue	15,000	-	-
Expenses			
Research and development expenses (Note 1)	(265,084)	(442,291)	(62,602)
Administrative expenses (Note 2)	(574,584)	(171,384)	(24,258)
Loss from operations	**(824,668)**	**(613,675)**	**(86,860)**
Interest income	12,818	18,955	2,683
Interest expense	(1,936)	(957)	(135)
Other gains, net	303	12,824	1,815
Fair value change of warrants	(43,854)	-	-
Loss before income tax expense	**(857,337)**	**(582,853)**	**(82,497)**
Income tax expense	-	-	-

Net loss attributable to I-MAB	**(857,337)**	**(582,853)**	**(82,497)**
Net loss attributable to ordinary shareholders	**(857,337)**	**(582,853)**	**(82,497)**
Net loss attributable to I-MAB	**(857,337)**	**(582,853)**	**(82,497)**
Foreign currency translation adjustments, net of nil tax	(4,972)	34,726	4,915
Total comprehensive loss attributable to I-MAB	**(862,309)**	**(548,127)**	**(77,582)**
Net loss attributable to ordinary shareholders	**(857,337)**	**(582,853)**	**(82,497)**
Weighted-average number of ordinary shares used in calculating net loss per share - basic and diluted	7,184,086	121,815,986	121,815,986
Net loss per share attributable to ordinary shareholders			
—Basic	(119.34)	(4.78)	(0.68)
—Diluted	(119.34)	(4.78)	(0.68)

Note:
(1) Includes share-based compensation expense of RMB308 and RMB132,724 (US$18,786) for the six months ended June 30, 2019 and 2020, respectively.
(2) Includes share-based compensation expense of RMB366,048 and RMB97,071 (US$13,739) for the six months ended June 30, 2019 and 2020, respectively.

I-MAB
Reconciliation of GAAP and Non-GAAP Results
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the six months ended June 30,		
	2019	2020	
	RMB	RMB	US$
GAAP net loss attributable to I-MAB	**(857,337)**	**(582,853)**	**(82,497)**
Add back:			
Share-based compensation expense	366,356	229,795	32,525
Non-GAAP adjusted net loss attributable to I-MAB	**(490,981)**	**(353,058)**	**(49,972)**
Non-GAAP adjusted net loss attributable to ordinary shareholders	**(490,981)**	**(353,058)**	**(49,972)**
Weighted-average number of ordinary shares used in calculating net loss per share - basic and diluted	7,184,086	121,815,986	121,815,986
Non-GAAP adjusted net loss per share attributable to ordinary shareholders			
—Basic	(68.34)	(2.90)	(0.41)
—Diluted	(68.34)	(2.90)	(0.41)

View original content to download multimedia:http://www.prnewswire.com/news-releases/i-mab-reports-financial-results-for-the-six-months-ended-june-30-and-provides-corporate-update-301120931.html

SOURCE I-Mab