UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of August 2021

Commission File Number: 001-39173

I-MAB

Suite 802, West Tower, OmniVision, 88 Shangke Road, Pudong District
Shanghai, 201210
People's Republic of China
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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, thereunto duly authorized.

I-MAB

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: Director and Chief Financial Officer

Date: August 12, 2021

Exhibit Index

Exhibit 99.1—Press Release

Exhibit 99.1

I-Mab Reports Positive Interim Analysis from Phase 2/3 Study of its GM-CSF Antibody Plonmarlimab (TJM2) to Treat Patients with Severe COVID-19

- *Interim analysis showed positive preliminary results for maintaining patients without mechanical ventilation and reducing the mortality rate, with shortened time to recovery and hospitalization duration*
- *A reduction in key pro-inflammatory cytokines and chemokines critically involved in cytokine release syndrome (CRS) was observed in patients treated with plonmarlimab compared to placebo*
- *Plonmarlimab treatment was well tolerated with no significant safety concerns in patients with severe COVID-19*
- *I-Mab plans to continue advancing the study in the U.S. and begins to explore other CRS-related opportunities*

SHANGHAI, China and GAITHERSBURG, MD. – August 11, 2021 – I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, today announced positive interim data from its U.S. phase 2/3 study (NCT04341116) of plonmarlimab (also known as TJM2 or TJ003234) for the treatment of cytokine release syndrome (CRS) in patients with severe COVID-19. Plonmarlimab was discovered and developed by I-Mab to target human granulocyte-macrophage colony-stimulating factor (GM-CSF), a cytokine that plays a critical role in acute and chronic inflammation.

COVID-19 virus (SARS-CoV-2), particularly the Delta variant, is known to cause a pathologic surge of circulating inflammatory cytokines termed cytokine release syndrome (CRS) or cytokine storm, which is responsible for complications and higher mortality associated with the disease. Plonmarlimab plays a critical therapeutic role in CRS through the inhibition of GM-CSF that acts at the upstream of the pathologic inflammatory cascade and is expected to be more efficacious in preventing and treating CRS.

"We are very excited about the data and plonmarlimab could be a very promising treatment for hospitalized patients with COVID-19," said Deepa Gotur, MD, associate professor of clinical medicine at Houston Methodist.

The ongoing U.S. phase 2/3 study is one of the first double-blind, placebo-controlled, randomized studies to evaluate the therapeutic role of GM-CSF antibody in severe COVID-19 patients. The study aimed to determine the safety, efficacy and effects on cytokine levels following a single dose of 6 mg/kg of plonmarlimab or placebo in patients with severe COVID-19.

The current interim analysis showed positive preliminary results in patients who were mechanical ventilation free (MVF) at baseline (N=91). Plonmarlimab treatment resulted in a higher MVF rate (83.6% vs 76.7%) by day 30, lower mortality rate (4.9% vs 13.3%) by day 30, higher recovery rates (68.9% vs 56.7% at day 14 and 80.3% vs 70.0% at day 30), as well as reduced time to recovery and hospitalization duration, as compared to placebo. The magnitudes of the clinical improvements are comparable to those observed with lenzilumab in a similar patient population.[1] Biomarker results were consistent with the observed clinical outcome and indicated patients treated with plonmarlimab had a reduction in plasma levels of pro-inflammatory cytokines and chemokines critically involved in CRS, including TARC, IP10, GCSF, IL10, IL6, MCP1, IL1RA, TNF-alpha but not interferon-gamma. A transient increase in Neutrophil to Lymphocyte Ratio (NLR) that is commonly associated with disease exacerbation was only observed in placebo. Plonmarlimab was well tolerated in all patients with no significant safety concerns.

1 https://www.medrxiv.org/content/10.1101/2021.05.01.21256470v1.full.pdf

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"Plonmarlimab has shown very promising results from the interim data analysis in our phase 2/3 trial, and we intend to continue advancing the study in the U.S. at this critical juncture of the COVID-19 pandemic and continue exploring other clinical opportunities associated with CRS," said Dr. Joan Shen, CEO of I-Mab.

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About Plonmarlimab

Plonmarlimab (or TJM2) is an internally discovered neutralizing antibody against human GM-CSF, an important cytokine that plays a critical role in chronic inflammation and destruction in autoimmune diseases such as RA GM-CSF can polarize macrophages into the pro-inflammatory M1 phenotype and is known to induce an inflammatory cascade involving other pro-inflammatory cytokines such as tumor-necrosis factor (TNF), interleukin-1 (IL-1), IL-6, IL-12, and IL-23. It is evident that GM-CSF plays a crucial role in the pathogenesis and disease progression of multiple autoimmune conditions.

Plonmarlimab specifically binds to human GM-CSF with high affinity and can block GM-CSF from binding to its receptor, thereby preventing downstream signalling and target cell activation. As a result, it can effectively inhibit inflammatory responses mediated by macrophages, neutrophils, and dendritic cells, leading to reduced tissue inflammation and damage.

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 transition from a clinical-stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facilities, and commercial capability. I-Mab has offices in Beijing, Shanghai, Hangzhou, Hong Kong, and Maryland, United States. For more information, please visit http://ir.i-mabbiopharma.com and follow I-Mab on LinkedIn, Twitter, and WeChat.

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I-Mab Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding data from the plonmarlimab phase 2/3 trial, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of plonmarlimab. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to I-Mab's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or NDA/BLA approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of I-Mab's drug candidates; I-Mab's ability to achieve commercial success for its drug candidates, if approved; I-Mab's ability to obtain and maintain protection of intellectual property for its technology and drugs; I-Mab's reliance on third parties to conduct drug development, manufacturing and other services; I-Mab's limited operating history and I-Mab's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in I-Mab's most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties, and other important factors in I-Mab's subsequent filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to I-Mab, and I-Mab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law.

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