



**I-MAB**  
BIOPHARMA

## **I-Mab Announces Positive Topline Phase 2 Results for Olamkicept in Ulcerative Colitis**

April 26, 2021

SHANGHAI and GAITHERSBURG, Md., April 26, 2021 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced positive topline results from its regional multi-center, randomized, double-blind and placebo-controlled phase 2 study (NCT03235752) evaluating the efficacy and safety of olamkicept (also known as TJ301) administered intravenously biweekly in patients with active ulcerative colitis (UC).

Olamkicept is the only clinical stage selective IL-6 inhibitor that works through the trans-signaling mechanism. IL-6 is an important driver cytokine in the propagation and maintenance of chronic inflammation in autoimmune diseases, such as UC.

The phase 2 study, one of the first placebo-controlled, proof-of-concept studies of an IL-6 inhibitor in UC, has met both its primary and key secondary efficacy endpoints, demonstrating significantly higher clinical response rates after 12 weeks of treatment in patients receiving 600 mg olamkicept compared to those on placebo ( $p=0.032$ ). Significantly more patients in the 600 mg olamkicept group achieved clinical remission and mucosal healing than in placebo ( $p<0.001$ ), two key secondary endpoints of the study. Olamkicept was well tolerated, and with a very acceptable safety profile. Detailed data analysis will be presented at Digestive Disease Week (DDW) 2021 in the U.S. in May and at European Crohn's and Colitis Organisation (ECCO) meeting in July 2021.

"We are very excited to see that olamkicept demonstrated significant clinical benefits for active UC patients in terms of safety and efficacy through this successful phase 2 study. This is the first demonstration that IL-6 blockade through the trans-signaling pathway plays a significant therapeutic role in UC. The study provides confidence for further clinical development of this differentiated IL-6 blocker as a treatment option for UC and IBD," said Prof. Minhu Chen, Chair of Gastroenterology and Hepatology and Vice President at the First Affiliated Hospital of Sun Yat-sen University, principal investigator of the study.

I-Mab entered into a license agreement with Ferring Pharmaceuticals to develop and commercialize olamkicept for Greater China and South Korea in 2016. On April 23<sup>rd</sup>, 2021, the Company and Ferring signed a memorandum of understanding (MoU) to explore a possible collaboration to advance the development and commercialization of olamkicept in US and Canada, the European Union and Japan, if so agreed.

"There is an unmet need in the management of inflammatory bowel disease, such as UC, as current pharmacological therapies have significant side effects and develop resistance over time," said Dr. Joan Shen, CEO of I-Mab. "The positive phase 2 clinical data support our belief that olamkicept has the potential to become standard of care in UC, and we are excited by the prospect of exploring a broader reach to patients globally and offer a new treatment option."

### **About Olamkicept**

Olamkicept is a homodimer of a fusion protein consisting of the extracellular domains of human glycoprotein130 ("gp130") and the fragment crystallizable (Fc) domain of human IgG1. It is the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism which is considered an important mediator of the proinflammatory effects of IL-6. The existing IL-6 or IL-6R blockers cause total inhibition of IL-6 signaling, including inhibition of homeostatic effects, and are associated with significant adverse events such as infection, gastrointestinal perforation and metabolic disturbances. Olamkicept, on the other hand, is expected to have more selective effect on the IL-6 driven inflammation and provide a better safety profile based on its mechanism of action and the data from preclinical and clinical studies. Olamkicept has the potential to be a best-in-class to treat UC and other autoimmune diseases where IL-6 is a critical inflammatory mediator. I-Mab acquired an exclusive license from Ferring Pharmaceuticals to develop and commercialize olamkicept in Greater China and South Korea with an option, on terms as further described in the licensing agreement, to expand I-Mab' rights to any of the mutually agreed upon countries from U.S, Canada, the European Union and Japan.

### **About the olamkicept Phase 2 clinical study**

The study is a global multicenter, randomized, double-blind, placebo-controlled phase 2 trial (NCT03235752). The primary efficacy endpoint is the percentage of subjects achieving a clinical response per Full Mayo Score at Week 12. The study was conducted at 27 sites in Mainland China, Taiwan and South Korea and enrolled 91 patients who had active ulcerative colitis with a full Mayo score  $\geq 5$ , a rectal bleeding subscore  $\geq 1$ , an endoscopy subscore  $\geq 2$ , and had an inadequate response with conventional UC therapy. Patients were randomized 1:1:1 to receive either olamkicept 300 mg biweekly, or olamkicept 600 mg biweekly or matching placebo, stratified by use of corticosteroids and prior biologics treatment. All endoscopic tests have been read and confirmed by an independent central review committee.

### **About ulcerative colitis**

Ulcerative colitis ("UC") is an inflammatory bowel disease ("IBD") that causes chronic and often relapsing inflammation and ulceration of the colon and rectum, resulting in gastrointestinal symptoms that greatly affect the quality of life of patients. Disease complications may include megacolon, inflammation of the eye, joints, or liver, and colon cancer. Currently, there is no curative treatment for UC especially for those with a moderate-

to-severe disease. There is a substantial unmet medical need in UC for a treatment agent(s) that is efficacious and safe through pathways beyond the traditional drug targets.

### **About I-Mab**

I-Mab (Nasdaq: IMAB) is an innovation-driven global biotech company focusing on discovery, development and soon commercialization of novel and highly differentiated biologics in immuno-oncology therapeutic area. The Company's mission is to bring transformational medicines to patients around the world through drug innovation. I-Mab's globally competitive pipeline of more than 15 clinical and pre-clinical stage drug candidates is driven by its internal R&D capability and global licensing partnerships, based on the Company's unique Fast-to-Proof-of-Concept and Fast-to-Market pipeline development strategies. The Company is now rapidly progressing from a clinical stage biotech company to a fully integrated global biopharmaceutical company with cutting-edge global R&D capabilities, a world-class GMP manufacturing facility and commercialization capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou and Hong Kong in China, and Maryland and San Diego in the United States. For more information, please visit <http://ir.i-mabbiopharma.com> and follow I-Mab on [LinkedIn](#), [Twitter](#) and [WeChat](#).

### **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 clinical trials for TJ301, potential implications of clinical data for patients, further development of TJ301 by I-Mab in additional countries, and anticipated clinical development, regulatory milestones and commercialization of TJ301. 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 the ability and timing of I-Mab and Ferring should they agree upon any additional countries to develop TJ301; the ability of I-Mab to demonstrate the safety and efficacy of TJ301; the clinical results for the drug candidate, which may not support further development or BLA approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of the drug candidate; the ability to achieve commercial success for the drug candidate, 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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