I-Mab Announces First Patient Dosed in U.S. Phase 1 Study of Protollin for the Treatment of Alzheimer's Disease

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SHANGHAI and GAITHERSBURG, Md., Dec. 8, 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 that the first patient had been dosed in the I-Mab and Nhwa-sponsored U.S. Phase I study of Protollin, an investigational drug being co-developed to treat Alzheimer's disease.

The Phase I trial conducted by Brigham and Women's Hospital is a randomized, double-blinded ascending dose study of the safety, tolerability, and immune effects of Protollin in patients with early symptomatic Alzheimer's disease.

"We are pleased to be working with Brigham and Women's Hospital and our other partners to advance Protollin into the clinic," said Dr. Jingwu Zang, Founder, Chairman and Director of I-Mab. "This is an important milestone in the quest to develop novel treatments for patients suffering from Alzheimer's disease and we look forward to continuing to support this global effort to develop novel therapies."

Protollin is a novel immunotherapy composed of outer membrane proteins of bacteria complexed with lipopolysaccharides (LPS), aimed at stimulating the innate immune system to activate a response against the build-up of beta amyloid protein plaques and subsequent tau tangles that are the hallmarks of Alzheimer's disease. The initial data support its potential application in treating Alzheimer's disease by modulating immune cells.

"The launch of the first human trial of the nasal vaccine Protollin for Alzheimer's is a remarkable milestone," said Howard L. Weiner, MD, co-director of the Ann Romney Center for Neurologic Diseases at the Brigham. "Over the last two decades, we've amassed preclinical evidence suggesting its potential. If clinical trials in humans show that Protollin is safe and effective, this could represent a novel therapy for people with Alzheimer's, and it could also be given early to help prevent Alzheimer's disease in people at risk."

The first patient dosed follows FDA acceptance of the Investigational New Drug (IND) submission for Protollin in July 2021. It also provides a step further in exploring novel therapies for Alzheimer's disease, which affects tens of millions of people worldwide.

Brigham and Women's Hospital and Inspirevax (formerly Biodextris) granted I-Mab and Jiangsu Nhwa Pharmaceutical Co. (Nhwa) global exclusive licenses to develop, manufacture, and commercialize Protollin, and Inspirevax will manufacture and supply Protollin for preclinical and clinical studies until the recruitment of the first patient in the Phase 1b Multiple Ascending Dose (MAD) study. I-Mab will develop and commercialize Protollin outside of the Greater China territory, while Nhwa will develop and commercialize the drug in the Greater China territory (i.e., mainland China, Hong Kong, Macau, and Taiwan).

About Protollin

Protollin is a novel immunotherapy aimed at stimulating the innate immune system. It is composed of outer membrane proteins of bacteria complexed with lipopolysaccharides (LPS). There are preclinical data indicating that it can modulate immune cells and has the potential to treat disorders with an immune component. Delivery of Protollin through nasal spray will enable the molecule reach brain and stimulate the expected immune response. The initial data support its potential application in neurodegenerative diseases such as Alzheimer's disease.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biopharma company focused on the discovery, development and commercialization of novel and highly differentiated biologics for immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's globally competitive pipeline of more than 20 clinical and preclinical-stage drug candidates is driven by its internal discovery and global partnerships for in-licensing, based on the Company's Fast-to-Proof-of-Concept and Fast-to-Market

development strategies. The Company is progressing from a clinical-stage biotech company into a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, a world-class GMP manufacturing facility, and commercial capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou, Guangzhou, Lishui 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.

Special Note Regarding Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements." You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on I-Mab, Jiangsu Nhwa, and Inspirevax's (formerly Biodextris) current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in filings with the U.S. Securities and Exchange Commission. I-Mab, Jiangsu Nhwa, and Inspirevax (formerly Biodextris) undertake 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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