



**I-MAB**  
BIOPHARMA

## **I-Mab Announces IND Approval by FDA to Initiate Phase 1 Study for Protollin for the Treatment of Alzheimer's Disease**

7月 30, 2021

- *Planning underway for a Phase 1 Trial to assess new immunotherapy aimed at stimulating the innate immune system to clear beta amyloid protein plaques in Alzheimer's Disease*

SHANGHAI and GAITHERSBURG, Md., July 30, 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 U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) submission for Protollin, an investigational drug to treat Alzheimer's disease, enabling a Phase 1 clinical trial to be initiated. Worldwide, around 50 million people are living with Alzheimer's disease or other dementias, with no cure available.

"Advancing Protollin into clinic is a critical milestone in the search to develop novel therapies for this devastating disease, and we are honored to be engaging in a planning process with partners around the globe and contributing our expertise," said Dr. Jingwu Zang, Founder, Chairman and Director of I-Mab.

Protollin is a new type of immunotherapy 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 cause memory loss.

Brigham and Women's Hospital and Inspirevax (formerly Biodextris) granted I-Mab and Nhwa global exclusive licenses to develop, manufacture, and commercialize Protollin, and Biodextris will manufacture and supply Protollin for preclinical and clinical studies until the recruitment of the first patient in the Phase 1b MAD study<sup>[1]</sup>. I-Mab will develop and commercialize Protollin outside of the Greater China territory, while Nhwa will develop and commercialize the drug in mainland China, Hong Kong, Macau, and Taiwan.

[1] <https://www.i-mabbiopharma.com/en/article-304.aspx>

### **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 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](#).

### **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.

**For more information, please contact:**

**I-Mab**

Jielun Zhu, Chief Financial Officer

E-mail: [jielun.zhu@i-mabbiopharma.com](mailto:jielun.zhu@i-mabbiopharma.com)

Office line: +86 21 6057 8000

Gigi Feng, Chief Communications Officer

E-mail: [gigi.feng@i-mabbiopharma.com](mailto:gigi.feng@i-mabbiopharma.com)

Office line: +86 21 6057 5709

**Investor Inquiries:**

The Piacente Group, Inc.

Emilie Wu

E-mail: [emilie@thepiacentegroup.com](mailto:emilie@thepiacentegroup.com)

Office line: + 86 21 6039 8363

 View original content to download multimedia: <https://www.prnewswire.com/news-releases/i-mab-announces-ind-approval-by-fda-to-initiate-phase-1-study-for-protollin-for-the-treatment-of-alzheimers-disease-301345030.html>

SOURCE I-Mab