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Innovent Biologics, Eli Lilly has announced that IBI301 has met pre-defined primary endpoints

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The details of these studies will be disclosed in future publications in scientific journals and conferences.



Innovent Biologics and Eli Lilly and Company has jointly announced that IBI301, a recombinant human-mouse chimeric anti-cell surface protein (anti-CD20) monoclonal antibody being co-developed as a potential biosimilar to rituximab, which is sold under the brand name MabThera/Rituxan has met pre-defined primary endpoints in two randomized clinical trials comparing IBI301 to rituximab, namely: a phase III clinical trial (CIBI301A301) in patients with diffuse large B-cell lymphoma (DLBCL) and a pharmacokinetic (PK) study (CIBI301A201) in patients with CD20-positive B-cell lymphoma. The details of these studies will be disclosed in future publications in scientific journals and conferences.

CIBI301A201 is a randomized, double-blinded, parallel, positive-controlled single-dose clinical trial in China with an enrollment of 181 patients which compares the PK profile, safety, tolerability, and immunogenicity of IBI301 with those of rituximab in patients with CD20-positive B-cell lymphoma. The primary objective of the study is to compare the PK profile of these two agents.

CIBI301A301 is a multi-center, randomized, double-blinded, parallel, positive-controlled phase III clinical trial in China with an enrollment of 420 patients which evaluates the efficacy and safety of IBI301 and rituximab in the first-line treatment of patients with newly diagnosed DLBCL. The objective of the study is to compare the clinical activity and safety between IBI301 and rituximab when each is used in combination with standard chemotherapy (CHOP) in patients with diffuse DLBCL. The primary endpoint is objective response rate (ORR).

"DLBCL is the most common type of lymphoma in China and rituximab is the standard treatment for DLBCL patients. The launch of a high quality rituximab biosimilar will improve drug accessibility and benefit more patients," said Professor Lugui Qiu from Blood Diseases Hospital, Chinese Academy of Medical Sciences.

"We are extremely happy that through the efforts of all investigators, the two key studies have both met the primary endpoints. This has laid a solid foundation for the next steps in the new drug application (NDA) of the biosimilar candidate. The Chinese DLBCL patients really need and deserve such a high-quality biological drug," said Professor Zhu Jun, Beijing Cancer Hospital.

"Malignant lymphoma is one of the top ten malignancies in China and incidences thereof are still rising and pose a heavy economic burden for the vast majority of patients. Anti-CD20 monoclonal antibodies are effective treatments for lymphoma. However, currently there is only one approved biosimilar in China. The results of clinical studies of IBI301, a potential biosimilar of rituximab, are encouraging. We hope that the launch of IBI301 in the China market will improve its affordability, so more patients with lymphoma can benefit from the drug," said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.

Dr. Wang Li, Senior Vice-President of Lilly China and Head of Lilly China Drug Development and Medical Affairs, commented, "The results of these studies have significant clinical value and show the outstanding research and development capabilities of Innovent. We hope that IBI301 can be approved soon in order to offer an affordable treatment option for lymphoma patients in China."

IBI301 is a biosimilar of rituximab, a recombinant human-mouse chimeric anti-CD20 monoclonal antibody for injection co-developed by Innovent and Lilly. Rituximab is a monoclonal antibody which binds to CD20 antigen on the surface of B lymphocytes and mediates complement-dependent cytotoxicity (CDC) and antibody-dependent cellular cytotoxicity (ADCC). The normal and malignant B cells in the mediator dissolve, thereby achieving an anti-tumor therapeutic effect.

Inspired by the spirit of "Start with Integrity, Succeed through Action," Innovent's mission is to develop and commercialize high quality biopharmaceutical products that are affordable to ordinary people. Established in 2011, Innovent is committed to developing, manufacturing and commercializing high quality innovative medicines for the treatment of oncology, autoimmunity and other major diseases. On October 31, 2018, Innovent was listed on the Main Board of the Stock Exchange of Hong Kong Limited with the stock code: 01801.HK.

Since it was founded, Innovent has developed a fully-integrated platform which includes R&D, CMC (Chemistry, Manufacturing, and Controls), clinical development and commercialization capabilities. Leveraging the platform, the company has built up a robust pipeline of 20 innovative assets in the fields of oncology, ophthalmology, autoimmunity, and cardiovascular diseases. Fourteen assets have entered into clinical development, four have entered Phase III clinical trials, two monoclonal antibodies have their New Drug Application (NDA) under review and have been granted with priority review status, and one, Tyvyt (sintilimab injection), is now approved for relapsed or refractory classical Hodgkin's lymphoma (r/r cHL).

Innovent has built an international team of employees with advanced talents in high-end biological drug development and commercialization, including many overseas experts. The company has also entered into strategic collaborations with Eli Lilly and Company, Adimab, Incyte, Hanmi and other international pharmaceutical companies. Innovent strives to work with all relevant parties to help advance China's biopharmaceutical industry, improve drug availability to ordinary people and enhance the quality of patients' lives.