

CHINA FDA ACCEPTS JHL'S FIRST CLINICAL TRIAL APPLICATION

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JHL Biotech Inc. (Stock Code: 6540.TWO) is announcing that its Clinical Trial Application (“CTA”) for use of JHL1101 in Phase 1 and Phase 3 clinical trials in Non-Hodgkin’s Lymphoma patients has been accepted by the China Food and Drug Administration (“CFDA”) (filing code: CXSL1700027 鄂). JHL is filing under the new guidelines for biosimilars issued in 2015.

JHL1101 is a proposed rituximab biosimilar that JHL is pursuing as part of its strategic biologics alliance with Sanofi, and it is the first product in JHL’s pipeline. Material used to support the CTA was manufactured at JHL’s facility in Wuhan, China, where JHL operates the world’s largest biopharmaceutical manufacturing facility that is based on single-use technologies. Rituximab is used to treat Rheumatoid Arthritis (“RA”) and Non-Hodgkin’s Lymphoma (“NHL”). In China, rituximab is used to treat NHL. Each year, about 4.3 million Chinese are diagnosed with cancer, and about 80,000 of these diagnoses are NHL.¹

JHL is developing biosimilars for Chinese and global markets. In addition to conducting trials in China, JHL is the only Greater China-based biosimilars developer to have received European Union and Taiwanese regulatory approval to conduct clinical trials of the proposed rituximab biosimilar: a randomised, double-blind, parallel group, multicentre study comparing the pharmacokinetics, pharmacodynamics, immunogenicity, safety, and efficacy of JHL1101 versus EU sourced MabThera® in anti-tumor necrosis factor (TNF)

¹ <http://onlinelibrary.wiley.com/doi/10.3322/caac.21338/full>

inadequate responder patients with moderate to severe rheumatoid arthritis.

According to Racho Jordanov, JHL's co-founder and CEO, "This submission represents years of work. It is a milestone for JHL and the first of many submissions to come. This is JHL's first step towards making an important oncology therapy more accessible and affordable to Chinese patients, and I am exceptionally proud of our fantastic team for making JHL1101 a reality."

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About JHL Biotech

JHL Biotech Inc. (Stock Code: 6540.TWO) is a biopharmaceutical startup founded by a group of industry veterans with deep experience in pharmaceutical development and operations. JHL is backed by premier financial firms, including Kleiner Perkins Caufield & Byers, Sequoia Capital, Biomark Capital, Milestone Capital, Fidelity, and the China Development Industrial Bank. JHL Biotech's mission is to provide the world with low-cost medicines of exceptional quality. JHL is focused on research and development of new protein-based therapies and biosimilars. JHL Biotech has two world-class facilities built in accordance with United States, European Union, and ICH cGMP regulations and standards. For more information, please visit www.jhlbiotech.com.