

CHINA CENTER FOR DRUG EVALUATION RECEIVES JHL1101 CLINICAL TRIAL APPLICATION FOR REVIEW

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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 is under review by the China Food and Drug Administration (“CFDA”) Center for Drug Evaluation (“CDE”). JHL is filing under the new technical guideline for biosimilars issued in 2015. The application was submitted to the CDE following data inspection of the manufacturing sites and nonclinical contract research sites by the Hubei province Food and Drug Administration.

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 trial of the proposed rituximab biosimilar: a randomised, double-blind, parallel group,

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

multicentre study comparing the pharmacokinetics, pharmacodynamics, immunogenicity, safety, and efficacy of JHL1101 versus EU sourced MabThera[®] in anti-tumor necrosis factor (TNF) inadequate responder patients with moderate to severe rheumatoid arthritis.

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Media Contact:

Gregory Manker

Phone: +886-909-780-862

gmanker@jhlbiotech.com

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.