



FOR IMMEDIATE RELEASE

JHL Biotech Taiwan Announces Successful Manufacture and Release of First 500L GMP Drug Substance For Phase 1 Clinical Trial

HSINCHU, TAIWAN – May 18, 2015 – JHL Biotech, Inc., an emerging biopharmaceutical development organization with integrated manufacturing capability, today announced that it has successfully completed the GMP manufacture and lot release of its first 500L scale batch from its Taiwan facility for a privately-held Chinese biotech company of its oncology monoclonal antibody product for use in Phase 1 clinical trials in Australia.

With extensive in-house analytical and QC assay, the complex project was completed in under 8 months which also included a technical transfer and implementation of analytical methods and process steps. JHL was also responsible for assay development, reference standard filling/qualification and implementing tight process controls to produce material matching the initial quality parameters. JHL also handled viral clearance and validation.

In addition to performing a variety of other project related activities for the client, the successful GMP lot release of the DS (Drug Substance) was a critical piece to a project which began with a technical transfer of a developed process re-assigned to JHL Biotech from a competitor operating a global Contract Manufacturing Organization (CMO). JHL Biotech views the successful transfer and manufacturing of this product to be a testament to its world-class biopharmaceutical capabilities, and is further validated by the same client placing orders for additional GMP lots and engaging JHL on another mission-critical oncological compound with additional services including process development, scale-up and GMP production.

“The release of GMP clinical material is an important milestone for our contract manufacturing operation,” said Racho Jordanov, President and CEO of JHL Biotech. “We are very pleased to deliver on our promise of manufacturing excellence for this very important client, and we look forward to repeating the same success for our future CMO clients.”

JHL Biotech is dedicated to providing world-class biological development and cGMP manufacturing services through any stage of the pre-clinical and clinical process. In its state of the art cGMP facilities in Taiwan at 500L scale, and in Wuhan starting from 3Q2016 at 2000L scale, JHL can provide DS under fully validated conditions that ensure the highest standards of safety and quality. JHL also seeks to continue developing its own proprietary biosimilars and novel therapeutic candidates for global licensing and/or commercialization.

For more information, please visit our website at www.jhlbiotech.com.

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