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Innovent declares positive result of IBI305, biosimilar to Avastin

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Innovent Biologics, Inc. (Innovent), a world-class China-based biopharmaceutical company that develops and commercializes high quality drugs, announced that IBI305, a recombinant humanized anti-VEGF monoclonal antibody is being developed as a potential biosimilar to Avastin (Bevacizumab).

It has met pre-defined primary endpoints in two randomized, head to head, clinical trials comparing IBI305 versus branded bevacizumab: a phase III clinical trial (CIBI305A301) in patients with advanced non-squamous non-small cell lung cancer (NSCLC) and a pharmacokinetic study (CIBI305A201) in healthy subjects. The details of these studies will be disclosed in future publications in scientific journals and conferences.

CIBI305A301 is a multi-center, randomized, double-blinded, parallel, positive-controlled phase III clinical trial that enrolled 450 patients to evaluate the efficacy and safety of IBI305 and bevacizumab in the first-line treatment of patients with advanced non-squamous NSCLC. The objective of the study is to compare the clinical activity and safety between IBI305 and bevacizumab when they are in combination with paclitaxel/carboplatin. The primary endpoint is objective response rate (ORR).

CIBI305A201 is a randomized, double-blinded, parallel, positive-controlled single-dose clinical trial to compare the pharmacokinetic profile, safety, tolerability, and immunogenicity between IBI305 and bevacizumab in 100 healthy subjects. The primary objective of the study is to compare the pharmacokinetic (PK) profile of these two agents.

"The current morbidity and mortality of malignant tumors in China are high, and anti-tumor treatment is a significant economic burden for millions of families. Anti-angiogenic drugs are effective anti-tumor treatments, but as of yet there are no approved

bevacizumab biosimilars in China. The clinical studies of IBI305, a potential biosimilar of bevacizumab, are encouraging. I hope that IBI305 will be launched soon into the Chinese market, so more cancer patients and their families can benefit from the use of this important medicine," said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.