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JHL Biotech submits application for Bevacizumab Biosimilar

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JHL Biotech recently announced that the China Food and Drug Administration (CFDA) have accepted for review JHL's Clinical Trial Application for a proposed bevacizumab biosimilar, JHL1149, to treat cancer.

JHL1149 is a biosimilar to bevacizumab and would provide an affordable alternative to treat several cancers, the most common of which are metastatic colorectal cancer, non-small cell lung cancer, and ovarian cancer, as well as cervical cancer, renal cell carcinoma, and glioblastoma.

JHL is planning to conduct a Phase I pharmacokinetic study in healthy volunteers in China followed by a multinational Phase III efficacy study in non-small cell lung cancer patients. Currently, a Phase I clinical trial for JHL1149 is ongoing in Europe. The data from these trials will support the global registration and commercialization of JHL1149.

Once approved, JHL1149 will be manufactured at JHL's facility in Wuhan, China, the world's largest biopharmaceutical manufacturing plant based on single-use technologies, which will provide a high-quality supply of products worldwide.

JHL1149 is an anti-vascular endothelial growth factor (anti-VEGF) monoclonal antibody. The reference biologic, bevacizumab, is marketed by Roche under the trade name, Avastin®.