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JHL Biotech Gets Positive CHMP Scientific Advice for Bevacizumab Biosimilar

10 August 2018 | News

JHL Biotech Receives Positive CHMP Scientific Advice for Global Phase III Clinical Trial of Proposed Bevacizumab Biosimilar to Treat Lung Cancer

JHL Biotech has received a positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) related to the EU approval pathway for its proposed bevacizumab biosimilar, JHL1149 to treat patients with non-small cell lung cancer (NSCLC).

The EMA, like other regulatory authorities such as the U.S. Food and Drug Administration and State Drug Administration of China (SDA), adopts the principle of a step-wise approach and the totality of the evidence from all studies in regulating the development and approval of biosimilars.

In its correspondence to JHL, the EMA confirmed it agrees with JHL's development approach, clinical development proposal, and study design of the global Phase III clinical study for JHL1149 in patients with non-small cell lung cancer (NSCLC).

Based on the EMA's review of these factors, the results of the Phase III clinical study will be acceptable for the submission of a Marketing Authorization Application as a biosimilar product, assuming the Phase III trial is completed successfully.