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ASIA EDITION

Everest Medicinesâ?? LEROCHOL BLA accepted in China for hypercholesterolemia

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The NMPA has accepted the biologics licence application for once-monthly PCSK9 inhibitor lerodalcibep, supported by Phase III data showing placebo-adjusted LDL-C reductions of up to 67%.



Everest Medicines has announced that China's National Medical Products Administration has accepted the Biologics License Application for LEROCHOL (lerodalcibep), a third-generation PCSK9 inhibitor for adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia.

The therapy is being developed for subcutaneous use as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol.

LEROCHOL is a small recombinant fusion protein comprising a PCSK9-binding Adnectin domain and human serum albumin. The candidate has an approximate molecular weight of 77 kDa and binds PCSK9 with picomolar affinity.

The recommended dosage is 300 mg administered subcutaneously once monthly. Everest Medicines said the therapy can be stored at room temperature at temperatures of up to 25°C for as long as three months before use.

The regulatory submission is supported by global clinical studies and a Phase III clinical trial conducted in China.

In the Chinese study, placebo-adjusted reductions in LDL-C from baseline reached 65.9% at week 12 and 67.0% for the mean of weeks 10 and 12.

More than 95% of participants receiving LEROCHOL achieved dual LDL-C targets specified under Chinese lipid-management guidelines.

Global clinical studies showed sustained LDL-C reductions of at least 60% among patients with cardiovascular disease or those at very-high or high cardiovascular risk, while patients with heterozygous familial hypercholesterolemia recorded reductions of 59%.

"The NMPA's acceptance of the BLA for LEROCHOL brings renewed hope to patients," said Professor Yong Huo, leading principal investigator and Chief Cardiology Expert at Peking University First Hospital.

"Results from the Phase 3 clinical trial demonstrated that Lerodalcibep significantly reduced LDL-C with a favorable safety and tolerability profile in Chinese patients with hypercholesterolemia. Its convenient monthly, single small-dose subcutaneous regimen, and up to 3-month room temperature stability address a significant unmet need in long-term lipid

management for patients at home or during travel.”

Everest Medicines said cardiovascular disease remains a major health burden in China, where an estimated 400 million people have dyslipidaemia but only around 14% receive lipid-lowering treatment.

LDL-C is a major modifiable risk factor for atherosclerotic cardiovascular disease and remains a primary target in domestic and international lipid-management guidelines.

“The BLA acceptance by the NMPA represents a significant step toward the commercialization of LEROCHOL in Greater China,” said Rogers Yongqing Luo, Chief Executive Officer of Everest Medicines.

“As a potential best-in-class PCSK9 inhibitor, LEROCHOL offers a novel treatment option with its robust lipid-lowering efficacy and favorable safety. It also provides extended room-temperature stability, enabling more convenient storage and travel, and supporting long-term lipid management at home.”

LEROCHOL has been approved by the US Food and Drug Administration and is under regulatory review by the European Medicines Agency, according to Everest Medicines.

The company expects potential approval in mainland China in 2027 and plans to continue advancing the regulatory and commercialisation process for LEROCHOL across Greater China.