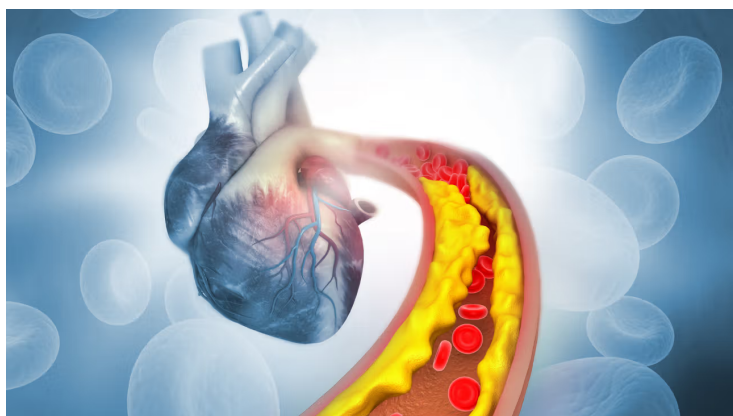


Everest Medicinesâ?? LEROCHOL BLA accepted in China for hypercholesterolemia

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The NMPA has accepted the Biologics License Application for once-monthly PCSK9 inhibitor lerodalcibep, with potential approval in mainland China targeted for 2027.



Everest Medicines has announced that China's National Medical Products Administration has accepted the Biologics License Application for LEROCHOL, or lerodalcibep, for the treatment of adults with hypercholesterolemia.

The investigational therapy is being reviewed for subcutaneous use as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia.

LEROCHOL is a third-generation PCSK9 inhibitor comprising a PCSK9-binding Adnectin domain and human serum albumin.

The approximately 77 kDa recombinant fusion protein binds PCSK9 with picomolar affinity and is designed for administration as a 300 mg subcutaneous dose once monthly.

The therapy can also be stored at room temperature of up to 25°C for as long as three months before use, potentially offering additional flexibility for patients managing long-term treatment at home or while travelling.

Cardiovascular disease remains a leading cause of mortality globally and in China, with elevated LDL-C representing one of the key modifiable risk factors for atherosclerotic cardiovascular disease.

Everest Medicines estimates that around 400 million people in China have dyslipidemia, while only approximately 14% currently receive lipid-lowering treatment.

The company said this treatment gap highlights continued unmet need for additional lipid-lowering options, particularly among patients who fail to achieve guideline-recommended LDL-C targets despite currently available therapies.

"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.”

He added that the therapy's once-monthly dosing and room-temperature stability could support longer-term lipid management outside the clinical setting.

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

In global studies, LEROCHOL produced sustained LDL-C reductions of at least 60% among patients with cardiovascular disease or those at very high or high cardiovascular risk.

Among patients with heterozygous familial hypercholesterolemia, LDL-C levels were reduced by 59%.

In the Chinese Phase III study, placebo-adjusted mean LDL-C reductions 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 under Chinese 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.”

Everest Medicines said the therapy could potentially receive approval in mainland China in 2027.

LEROCHOL has already received approval from the US Food and Drug Administration and is currently under regulatory review by the European Medicines Agency.

The Chinese filing also strengthens Everest Medicines' cardiovascular, kidney and metabolic disease portfolio as the company seeks to expand its presence in the CKM therapeutic area.

The company plans to continue advancing regulatory and commercial preparations for LEROCHOL across Greater China while expanding access to the therapy if approved.