

Everest Medicines announces NMPA acceptance of LEROCHOL BLA for hypercholesterolemia

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The application for the once-monthly PCSK9 inhibitor lerodalcibep is supported by global trials and a Phase 3 study in Chinese patients with hypercholesterolemia.



Everest Medicines announced on June 26, 2026, that China's National Medical Products Administration (NMPA) accepted the Biologics License Application (BLA) for LEROCHOL (lerodalcibep), a third-generation PCSK9 inhibitor, for subcutaneous use as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). The on-schedule acceptance underscores the Company's disciplined execution of its clinical and regulatory strategy, and marks another key R&D milestone for 2026.

LEROCHOL is a novel, third-generation small recombinant fusion protein therapeutic agent comprised of a proprotein convertase subtilisin/kexin type 9 (PCSK9)-binding domain (Adnectin) and human serum albumin (HSA) with an approximate molecular weight of 77 kDa and binds PCSK9 with picomolar affinity. The recommended dosage of LEROCHOL is 300 mg administered subcutaneously once monthly. LEROCHOL may be kept at room temperature up to 25°C for up to 3 months prior to use. These features make LEROCHOL a unique alternative to other PCSK9 inhibitors.

CVD remains the leading cause of death globally and in China. Extensive studies have confirmed that LDL-C is one of the most critical and modifiable risk factors for atherosclerotic cardiovascular disease (ASCVD). It has been identified as the primary intervention target for ASCVD prevention and treatment in both domestic and international lipid management guidelines. Despite the availability of existing lipid-lowering therapies, many patients with or at risk of CVD, including those with familial hypercholesterolemia (FH), still fail to achieve updated guideline-recommended LDL-C targets, highlighting the urgent need for more innovative treatment options. Despite an estimated 400 million individuals in China with dyslipidemia, only around 14% receive lipid-lowering treatment, reflecting low penetration and significant unmet medical need.

"The NMPA's acceptance of the BLA for LEROCHOL brings renewed hope to patients," said Professor Yong Huo, the leading principal investigator, Chief Cardiology Expert from 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. We hope LEROCHOL will soon be available to more patients."

"The BLA acceptance by the NMPA represents a significant step toward the commercialization of LEROCHOL in Greater China," said Mr. 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. With the potential for approval in mainland China in 2027, we will continue to expand access to LEROCHOL across Greater China, helping more patients benefit from this innovative therapy.”

The application is based on results from multiple global clinical trials as well as a Phase 3 clinical trial in China. In global clinical trials, LEROCHOL demonstrated sustained LDL-C reductions of ~60% in patients with, or at very-high or high risk of CVD and 59% in those with HeFH who have more severe LDL-C elevations. Results from the Phase 3 clinical trial of LEROCHOL in China showed that LEROCHOL significantly reduces LDL-C levels. Mean placebo-adjusted LDL-C reductions from baseline in the co-primary endpoints were 65.9% at week 12 and 67.0% for the mean of weeks 10 and 12. Over 95% of participants on LEROCHOL achieved dual Chinese lipid management guideline LDL-C targets.

At the time of the announcement, Everest Medicines stated that the U.S. Food and Drug Administration (FDA) had approved LEROCHOL and that it was under regulatory review by the European Medicines Agency (EMA).

From the perspective of the Company’s overall strategic roadmap, the acceptance of the BLA for LEROCHOL marks an important milestone in Everest Medicines’ continued efforts to deepen its strategic presence in the cardiovascular, kidney and metabolic (CKM) disease area. It will further enrich the Company’s innovative portfolio in the CKM field and provide a new growth driver for future commercialization. The timely acceptance of the BLA once again demonstrates the Company’s disciplined execution capabilities in advancing its established clinical and regulatory strategy. Looking ahead, Everest Medicines will continue to steadily advance the regulatory and commercialization process for LEROCHOL in Greater China, with the goal of bringing this innovative treatment option to patients as early as possible and further strengthening the Company’s overall competitiveness in the CKM field.