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FOR IMMEDIATE RELEASE

LIB Therapeutics and Sun Pharma Announce Global Licensing, Commercialization and Manufacturing Agreement for Lerodalcibep, a PCSK9 Inhibitor, Ex-US and China; Lyrokaul (lerodalcibep) Approved in the EU

Mumbai, India and Cincinnati, Ohio, United States, September 28, 2026 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715; together with its subsidiaries and/or associated companies, "Sun Pharma") and LIB Therapeutics Inc. ("LIB") today announced:

- An exclusive licensing agreement granting Sun Pharma rights to commercialize and manufacture lerodalcibep worldwide, excluding the United States and China.
- Lyrokaul (lerodalcibep), a once-monthly PCSK9 inhibitor for LDL-C lowering, comes with 6-month EU ambient storage; received EU approval on September 21, 2026.
- Strengthens Sun Pharma's Innovative Medicines portfolio through access to a US$3.7 billion PCSK9 market Ex-US and China, growing at 38% CAGR; global PCSK9 market approaching US$7 billion in 2026.[1]
- LIB will receive an upfront and future milestone payments, together with royalties based on net sales in the licensed territories.

Lerodalcibep is approved in the EU under the brand name Lyrokaul for the treatment of adult patients with hypercholesterolaemia and mixed dyslipidaemia. In the United States, it is US FDA-approved under the brand name Lerochol 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 partnership helps address a significant global unmet need in cardiovascular care. Many patients at high or very high cardiovascular risk remain above recently updated and more globally harmonized 2026 guideline-recommended LDL-cholesterol (LDL-C) goals despite treatment. In the DA VINCI observational study across 18 European countries, only 33% of patients assessed on stable oral lipid-lowering therapy achieved their risk-based 2019 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) LDL-C goals.[3]

Treatment guidelines now emphasise both additional LDL-C reductions and lower targets for patients at high and very high cardiovascular risk, with additional therapies when statins alone are insufficient. PCSK9 inhibitors provide the efficacy and safety to achieve these goals.[4] This gap between treatment goals and real-world control reinforces the opportunity for Sun Pharma and LIB to broaden access to innovative lipid-lowering care across Europe and Sun's world-wide licensed markets.

"Once-monthly lerodalcibep dosing, with robust LDL-C reduction and the added benefits of a small-volume injection and six-month ambient storage, simplifies treatment for patients and offers greater convenience", said Kirti W Ganorkar, Managing Director of Sun Pharma. "This agreement marks a significant step in strengthening our global Innovative Medicines portfolio, particularly in cardiovascular care. With exclusive rights outside the United States and China, we look forward to expanding access to this important treatment option for patients globally."

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"LIB is extremely pleased to partner with Sun Pharma, a well-established global pharmaceutical company with a growing focus on innovative medicines," said Evan Stein, MD, PhD, Chief Operating and Scientific Officer and co-founder of LIB Therapeutics. "Sun Pharma's international presence and experience in building global innovative brands make it an ideal partner to bring lerodalcibep to more patients. Together, we aim to expand access for patients with cardiovascular disease, or at high cardiovascular risk, who need substantial additional LDL-cholesterol reductions despite existing treatment."

The agreement establishes a significant new growth platform for Sun Pharma in a large and rapidly expanding market. According to IQVIA, the PCSK9 inhibitor market outside the United States and China reached US$ 3.7 billion in the period ending Q2 2026 (MAT Q2 2026), growing at 38% CAGR over the preceding two years. Europe alone accounted for US$ 2.9 billion PCSK9 inhibitor market in MAT Q2 2026.[1]

Agreement terms
LIB will receive an upfront and future milestone payments, together with royalties based on net sales in the licensed territories. Other terms of the agreement are confidential. Sun Pharma will be responsible for pursuing regulatory approvals in licensed territories where approval has not yet been obtained.

About lerodalcibep[2]
Lerodalcibep is a novel antibody-mimetic biologic and recombinant fusion protein that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9). It helps deliver sustained reductions in low-density lipoprotein cholesterol (LDL-C), often called "bad" cholesterol, with once monthly 300 mg/1.2 mL subcutaneous injection.

Recently, lerodalcibep has received marketing authorisation from European Medicines Agency under the brand name Lyrokaul. The EU label permits storage in the original carton at room temperature up to 25°C for up to six months after removal from refrigeration, offering flexibility for patients at home and while travelling.

In the United States, lerodalcibep is approved by the US FDA under the brand name Lerochol in both autoinjector and prefilled-syringe (PFS) presentations.

SELECT CLINICAL PARTICULARS (For more information, please see full Lyrokaul Product Information[2] in EU Commission Website)

Therapeutic indications
LYROKAUL is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated.

Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in package leaflet.

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Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Excipients with known effect

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Polysorbate 80

This medicinal product contains 0.24 mg polysorbate 80 (E 433) per dose. Polysorbates may cause allergic reactions.

Renal impairment

LYROKAUL should be used with caution in patients with severe renal impairment or end-stage renal disease. LYROKAUL has not been studied in these populations.

Severe hepatic impairment or active liver disease

LYROKAUL has not been studied in patients with severe hepatic impairment or active liver disease. LYROKAUL should only be used in these patients if the anticipated clinical benefit outweighs the risk.

Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Fertility, pregnancy and lactation

Pregnancy

There is no data from the use of lerodalcibep in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of LYROKAUL during pregnancy.

Breast-feeding

It is unknown whether lerodalcibep is excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of lerodalcibep in milk. A risk to the newborns/infants cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from LYROKAUL therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

No data on the effect of lerodalcibep on human fertility are available. Animal fertility studies were not performed, however no effects were seen on surrogate markers of fertility in animal studies.

Effects on ability to drive and use machines

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LYROKAUL has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions occurring in patients treated with lerodalcibep are injection site reaction (6.7%), injection site erythema (3.6%), and injection site bruising (1.6%).

Tabulated list of adverse reactions

Adverse reactions are presented by MedDRA system organ class in Table 1. Frequency categories are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000) and not known (cannot be estimated from the available data.

Adverse reactions

System organ class	Adverse reaction	Frequency
General disorders and administration site conditions	Injection site reactions[1]	Common
[1] See section "Description of selected adverse reactions"		

Description of selected adverse reactions

Injection site reactions

Injection site reactions occurred in 11.6% of patients treated with lerodalcibep in the pivotal studies. The most frequently occurring injection site reactions in patients treated with lerodalcibep were injection site reaction (6.7%), injection site erythema (3.6%), injection site pruritis (1.0 %) and injection site bruising (1.6%). The proportion of patients who discontinued treatment due to injection site reactions was 1.0%. Adverse reactions were generally mild or moderate in severity, 0.2 % injection site reactions were severe, transient, resolved and did not lead to discontinuation of study drug.

Immunogenicity

Anti-drug antibody (ADA) responses, including neutralising antibodies (Nab), were low titer and did not appear to have a clinically meaningful impact on the efficacy or safety of lerodalcibep, except for a higher rate of injection site reactions in patients with treatment emergent ADA compared to patients who were ADA negative.

* The excluded China territory comprises mainland China, Hong Kong, Macau and Taiwan.
# Worldwide rights exclude the United States and China. Certain other excluded territories, limited in number, will be covered through separate agreements between Sun and LIB.

[1] Source: IQVIA, PCSK9 inhibitor sales at manufacturer prices in US dollars, MAT Q2 2026; two-year CAGR from MAT Q2 2024 to MAT Q2 2026. Market analysis excludes the United States, Puerto Rico and China. Figures are rounded.

[3] Ray KK, Molemans B, Schoonen WM, et al. EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care: the DA VINCI study. Eur J Prev Cardiol. 2021;28(11):1279-1289. doi:10.1093/eurjpc/zwaa047. The 2019 goals were applied retrospectively to data collected in 2017-2018; the 33% figure relates to patients assessed on stable therapy.

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[4] Mach F, Koskinas KC, Roeters van Lennep JE, et al. 2025 Focused Update of the 2019 ESC/EAS Guidelines for the management of dyslipidaemias. Eur Heart J. 2025;46(42):4359-4378. doi:10.1093/eurheartj/ehaf190.

About LIB Therapeutics

LIB Therapeutics Inc is a privately-held, commercial-stage biopharmaceutical company dedicated to bringing novel, highly effective, and safe therapies to help the millions of patients with cardiovascular disease and familial hypercholesterolemia finally achieve their LDL-C goals.

LIB was advised and assisted by Greenhill & Co investment bank UK.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)

Sun Pharma is a leading global pharmaceutical company with a presence in Innovative Medicines, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Innovative Medicines portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for about 22% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across five continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on LinkedIn & X (formerly Twitter).

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