Everest Medicines and Kezar Life Sciences Receive IND Approval from China NMPA for PALIZADE Trial in Lupus Nephritis

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SHANGHAI & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 26, 2024-- Everest Medicines (HKEX 1952.HK) and Kezar Life Sciences, Inc. (Nasdaq: KZR) announced today that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved Kezar's investigational new drug (IND) application for initiation of the Phase 2b PALIZADE trial in China of zetomipzomib in patients with lupus nephritis (LN). Zetomipzomib is a novel, first-in-class, selective immunoproteasome inhibitor with broad therapeutic potential across multiple autoimmune diseases.

Everest will join Kezar and enroll patients in China as part of the ongoing PALIZADE trial, a global, placebo-controlled Phase 2b clinical trial evaluating the efficacy and safety of two dose levels of zetomipzomib or placebo in patients with active LN. In September 2023, Everest obtained exclusive rights to develop and commercialize zetomipzomib in Greater China, South Korea and Southeast Asia. LN is the most common secondary immune-mediated glomerular disease, which may gradually lead to kidney failure. There are an estimated 400,000-600,000 LN patients in China.

"With the approval of the zetomipzomib IND in China, Everest now has three medicines in the renal space either commercialized or in clinical development. We are excited about the initiation of this clinical trial with the potential to benefit patients with LN experiencing critical unmet medical needs," said Rogers Yongqing Luo, Chief Executive Officer of Everest Medicines. "We intend to leverage our expertise in clinical development, regulatory filings and our newly established commercial infrastructure in China to advance the development of zetomipzomib. We look forward to working closely with Kezar on enrolling the PALIZADE trial and furthering Everest's leadership position in renal and autoimmune diseases in Asia."

"This important milestone demonstrates that Everest is the ideal regional partner for Kezar in our efforts to develop zetomipzomib," said Christopher Kirk, Ph.D., Chief Executive Officer of Kezar. "We will continue to work with the outstanding team at Everest to help drive enrollment in PALIZADE and get zetomipzomib to even more patients in need in Asia."

PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, randomly assigned to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53. The primary efficacy endpoint is the proportion of patients who achieve a complete renal response (CRR) at Week 37, including a urine protein-to-creatine ratio (UPCR) of 0.5 or less without receiving rescue or prohibited medications.

About Zetomipzomib

Zetomipzomib (KZR-616) is a novel, first-in-class, selective immunoproteasome inhibitor with broad therapeutic potential across multiple autoimmune diseases. Preclinical research demonstrates that selective immunoproteasome inhibition results in a broad anti-inflammatory response in animal models of several autoimmune diseases, while avoiding immunosuppression. Data generated from Phase 1 and Phase 2 clinical trials provide evidence that zetomipzomib exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases.

About Everest Medicines

Everest Medicines is a biopharmaceutical company focused on discovering, developing, manufacturing and commercializing transformative pharmaceutical products and vaccines that address critical unmet medical needs for patients in Asian markets. The management team of Everest Medicines has deep expertise and an extensive track record from both leading global pharmaceutical companies and local Chinese pharmaceutical companies in high-quality discovery, clinical development, regulatory affairs, CMC, business development and operations. Everest Medicines has built a portfolio of potentially global first-in-class or best-in-class molecules in the company's core therapeutic areas of renal diseases, infectious diseases and autoimmune disorders. For more information, please visit its website at www.everestmedicines.com.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel treatments for immune-mediated and oncologic disorders. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated in a Phase 2b clinical trial for lupus nephritis and a Phase 2a clinical trial for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. Kezar's oncology product candidate, KZR-261, targeting the Sec61 translocon and protein secretion pathway, is being evaluated in an open-label dose-escalation Phase 1 clinical trial to assess safety, tolerability and preliminary tumor activity in solid tumors. For more information, visit www.kezarlifesciences.com, and follow us on LinkedIn, Facebook, Twitter and Instagram.

Forward-Looking Statements:

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "confident", "potential" and similar statements (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the companies' expectations and assumptions as of the date of this press release. Forward-looking statements contained in this press release include, but are not limited to, statements about the clinical development of zetomipzomib, the initiation, timing and enrollment of clinical trials, the clinical development and therapeutic potential of zetomipzomib, and the likelihood of obtaining regulatory approval of zetomipzomib.

Such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, or other factors, some of which are beyond the control of the companies and are unforeseeable. Therefore, the actual results may differ from those in the forward-looking statements as a result of various factors and assumptions, such as future changes and developments in the companies' business, competitive environment, regulatory environment, political, economic, legal and social conditions. Except as required by law, Everest and Kezar, as well as their affiliates, directors, officers, advisors or representatives, assume no obligation to update or revise forward-looking statements to reflect new information, future events or circumstances, even as new information becomes available.

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Investor and Media Contact:
Leah Liu
Vice President, Corporate Affairs
Everest Medicines
ir@everestmedicines.com
pr@everestmedicines.com

Gitanjali Jain
Vice President, Investor Relations and External Affairs
Kezar Life Sciences, Inc.
gjain@kezarbio.com

Source: Kezar Life Sciences, Inc.