Everest Medicines Limited
雲頂新耀有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1952)

VOLUNTARY ANNOUNCEMENT BUSINESS UPDATE ON THE APPROVAL OF NEW DRUG APPLICATION IN CHINA FOR NEFECON® FOR THE TREATMENT OF PRIMARY IMMUNOGLOBULIN A NEPHROPATHY IN ADULTS AT RISK OF DISEASE PROGRESSION

This announcement is made by Everest Medicines Limited (the "**Company**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update.

The board of directors of the Company (the "**Board**") is pleased to announce that the National Medical Products Administration ("**NMPA**") of China has approved the New Drug Application ("**NDA**") for Nefecon® for the treatment of primary immunoglobulin A nephropathy ("**IgAN**") in adults at risk of disease progression in China.

Nefecon® is the first ever treatment for IgAN approved by the U.S. Food and Drug Administration and European Medicines Agency, and the NDA approval by NMPA marks a new era for IgAN treatment in China. China has the highest prevalence of primary glomerular diseases in the world with an estimated 5 million IgAN patients. Current non-targeted treatment options for IgAN, such as RAS inhibitors, are used off-label and do not fundamentally alter disease progression. Untreated IgAN patients are at significant risk of kidney failure, which may require dialysis or kidney transplant. There is a very large unmet medical need among IgAN patients.

The global Phase 3 NefIgArd clinical trial was a randomized, double-blind, multicenter study that evaluated the efficacy and safety of Nefecon® at a once-daily dose of 16 mg, compared to placebo in adult patients with primary IgAN on optimized RASi therapy. In the global study, Nefecon® demonstrated a highly statistically significant and clinically relevant benefit compared to placebo in estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment with Nefecon® and 15-months of follow-up off drug, equivalent to approximately 12.8 years delay in disease progress to end stage renal disease.

The reduction in urine protein creatinine ratio (UPCR) observed with Nefecon® treatment was also durable and the proportion of patients with microhematuria in the Nefecon group declined. Results from Chinese subpopulation analysis demonstrated numerically greater magnitude of Nefecon® treatment effect compared with placebo in kidney function, proteinuria and microhematuria.

The NDA approval further establishes our leadership position in nephrology. While the Company will actively prepare for the commercial launch of Nefecon® and bring this first-in-disease therapy to patients in China as soon as possible.

INFORMATION ABOUT IgAN

IgAN is a progressive, chronic autoimmune disease that attacks the kidneys and occurs when galactose-deficient IgA1 is recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney. This deposition in the kidney can lead to progressive kidney damage and potentially a clinical course resulting in end- stage renal disease. IgAN most often develops between late teens and late 30s. IgAN patients are at imminent risk of progressing to end-stage renal disease, which may then require dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life.

INFORMATION ABOUT NEFECON®

Nefecon® is a patented oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. The formulation is designed as a delayed release capsule that is enteric coated so that it remains intact until it releases budesonide to the distal ileum. Each capsule contains coated beads of budesonide that target mucosal B-cells present in the ileum where the disease originates, as per the predominant pathogenesis models. In June 2019, the Company entered into an exclusive, royalty-bearing license agreement with Calliditas, which gives the Company exclusive rights to develop and commercialize Nefecon® in Mainland China, Hong Kong, Macau, Taiwan and Singapore. The agreement was extended in March 2022 to include South Korea as part of the Company's territories. Nefecon® received NDA approval in Macau in October 2023 and in China in November 2023.

Cautionary statement: We cannot guarantee that we will be able to develop, or ultimately market, Nefecon® successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By order of the Board
Everest Medicines Limited
Wei Fu
Chairman and Executive Director

Hong Kong, 24 November 2023

As at the date of this announcement, the Board comprises Mr. Wei Fu as Chairman and Executive Director, Mr. Yongqing Luo and Mr. Ian Ying Woo as Executive Directors, Mr. Yubo Gong and Ms. Lan Kang as Non-executive Directors, and Ms. Hoi Yam Chui, Mr. Yifan Li and Mr. Shidong Jiang as Independent Non-executive Directors.