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**EVEREST MEDICINES**

**云 頂 新 耀**

**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 RECOMMENDED BREAKTHROUGH THERAPY DESIGNATION FOR NEFECON FOR THE TREATMENT OF IGA NEPHROPATHY**

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 China Center for Drug Evaluation (“**CDE**”) of the National Medical Products Administration (“**NMPA**”) has recommended Breakthrough Therapy Designation (“**BTB**”) for Nefecon for the treatment of IgA Nephropathy (“**IgAN**”).

Nefecon is a potential first-in-disease, oral, targeted-release formulation of budesonide and is currently being investigated in a Phase 3 global registrational study NefIgArd, to evaluate its efficacy and safety in patients with primary IgAN. The Company is currently enrolling patients as part of the NefIgArd clinical trial to support approval for IgAN patients in China.

The Company’s licensing partner, Calliditas Therapeutics AB (NASDAQ: CALT) (“**Calliditas**”) reported positive topline results on November 8, 2020 from Part A of the global NefIgArd trial demonstrating Nefecon met its primary endpoint of a statistically significant reduction in urine protein creatinine ratio, or proteinuria, after 9 months of treatment, with significant continued improvement at 12 months. In addition, Nefecon has been granted Orphan Drug Designation for the treatment of IgAN by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

BTB, which is part of the recently revised Drug Registration Regulation, is designed to expedite the development and review of therapies in China that are being developed for treatment of serious diseases for which there is no existing treatment and where preliminary evidence indicates advantages of the therapy over current available treatment options.

## INFORMATION ABOUT NEFECON

Nefecon, an oral, targeted-release formulation of budesonide, is a potential first-in-disease product for the treatment of IgA nephropathy. This novel formulation delivers budesonide to the Peyer's patch in the ileum, which is responsible for the production of secretory immunoglobulin A (IgA). Treatment with Nefecon was previously demonstrated to cause a statistically significant reduction in proteinuria levels and stabilization of eGFR, compared to placebo, in a randomized, double-blind Phase 3 clinical trial conducted by our partner Calliditas Therapeutics AB (Nasdaq: CALT). Nefecon has been granted Orphan Drug Designation for the treatment of IgAN by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). 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.

## INFORMATION ABOUT IGA NEPHROPATHY

IgA Nephropathy (IgAN) a leading cause of chronic kidney disease (CKD) and renal failure, is a chronic, progressive, autoimmune disease associated with progressive renal impairment. A central finding in patients with IgAN is the presence of circulating and glomerular immune complexes comprised of galactose-deficient IgA1, an IgG autoantibody directed against the hinge region O-glycans, and C3. Glomerular sclerosis, renal interstitial fibrosis, renal dysfunction, proteinuria and hypertension are associated with disease progression. 50% of IgAN patients will develop end stage renal disease within 30 years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life. Currently, there are no approved treatments for IgAN in China and globally.

**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, December 2, 2020

*As at the date of this announcement, the board of directors of the Company comprises Mr. Wei Fu as Chairman and Executive Director, Dr. Kerry Levan Blanchard, Mr. Ian Ying Woo and Mr. Xiaofan Zhang as Executive Directors, Mr. Yubo Gong as Non-executive Director, and Mr. Bo Tan, Mr. Yifan Li and Mr. Shidong Jiang as Independent Non-executive Directors.*