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ASIA EDITION

Everest Medicines announces major regulatory updates in Taiwan and South Korea

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Receives accelerated review and approval process for Nefecon in Taiwan and South Korea

China-based biopharma firm Everest Medicines has announced that the Taiwan Food and Drug Administration and Ministry of Food and Drug Safety in South Korea have granted fast-tracked approval process to Nefecon.

Nefecon is the firm's lead product in the renal disease portfolio as a first-in-disease treatment for primary immunoglobulin A nephropathy (IgAN) and a New Drug Application (NDA) has been accepted in mainland China.

Rogers Yongqing Luo, Chief Executive Officer of Everest Medicines said, "While primary IgAN has much higher prevalence in Asia than elsewhere in the world, there are no established treatments for patients living with the chronic condition, underscoring the significant and urgent unmet need for this innovative medicine."

The Taiwan Food and Drug Administration has granted Accelerated Approval Designation (AAD) to Nefecon, which will enable NDA submission and priority review of Nefecon based on topline results from Part A of NefIgArd, the pivotal global Phase 3 clinical trial.

Meanwhile, the Ministry of Food and Drug Safety in South Korea granted orphan drug designation (ODD) for Nefecon, which will significantly accelerate NDA filing and approval with an increased probability of priority review designation.

Nefecon is approved and marketed in the US under the name TARPEYO and in the EU as Kinpeygo.