PRESS RELEASE

Rila Therapeutics Announces First Patient Enrolled in Phase II Clinical Trial of Novel HIPK2 Allosteric Inhibitor RLA-23174

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Rila Therapeutics recently announced that the first patient has been successfully enrolled in the Phase II clinical trial of RLA-23174 tablets, its novel small-molecule HIPK2 allosteric inhibitor. The study is being led by Academician Hou Fanfan and Professor Xu Zhongyuan of Nanfang Hospital, Southern Medical University.

The etiology and mechanisms of chronic kidney disease (CKD) are complex and remain incompletely understood. However, as the disease progresses, patients inevitably develop renal fibrosis and other complications, ultimately progressing to end-stage renal disease.

RLA-23174 is a potential first-in-class (FIC) drug that precisely inhibits the TGF-β/Smad3 fibrotic signaling pathway by modulating the interaction between HIPK2 and Smad3, thereby suppressing fibrosis and offering a potential new therapeutic option for CKD.

There are currently no approved clinical products targeting HIPK2. The successful enrollment of the first patient for RLA-23174 marks a key milestone in the clinical development of this potential first-in-class CKD therapy, which may bring a new innovative treatment option to patients as early as possible.

About RLA-23174

RLA-23174 is an oral small-molecule drug in clinical development and a novel allosteric inhibitor targeting homeodomain-interacting protein kinase 2 (HIPK2). Unlike conventional kinase inhibitors that directly block kinase catalytic activity, RLA-23174 selectively modulates the TGF-β/Smad3 fibrotic signaling pathway by

regulating the interaction between HIPK2 and the downstream key transcription factor Smad3. This differentiated mechanism of action is designed to inhibit the progression of renal fibrosis while potentially offering improved safety and tolerability.

In preclinical studies, RLA-23174 has demonstrated antifibrotic and renoprotective effects in multiple kidney disease models, including IgA nephropathy, diabetic kidney disease, and focal segmental glomerulosclerosis (FSGS). In the completed Phase I clinical trial in healthy volunteers, RLA-23174 demonstrated a favorable safety and tolerability profile, as well as predictable pharmacokinetic characteristics, providing core support for subsequent clinical development.

RLA-23174 is currently being evaluated in an ongoing Phase II clinical trial in patients with chronic kidney disease. The trial is designed to assess the safety, tolerability, and preliminary efficacy of RLA-23174, and to characterize its dose-response relationship, providing a basis for subsequent pivotal clinical trials.

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