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TransThera gets IND nod for clinical studies for CHF drug

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TransThera Biosciences Co. Ltd, a clinical-stage biotechnology company based in Nanjing, China, has announced that the U.S. Food and Drug Administration (FDA) has granted the company's Investigational New Drug (IND) application for TT-00920, a novel small molecule inhibitor of Phosphodiesterase 9 (PDE 9) for the treatment of chronic heart failure (CHF).

Under this IND, TransThera will initiate a Phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TT-00920 in healthy volunteers. The trial is expected to initiate in early 2020.

"IND approval for TT-00920 is an important milestone for TransThera," said Dr. Frank Wu, Founder and CEO of TransThera. "We believe that TT-00920 has potential to be a new transformative treatment option for patients suffering from chronic heart failure, particularly for HFpEF (heart failure with persevered ejection fraction), a predominant form of heart failure with no disease-modifying treatment options. We look forward to working with patients and physicians to evaluate the potential of TT-00920 in clinic."

TT-00920 is an investigational, highly potent and selective PDE9 inhibitor for the treatment of chronic heart failure. PDE9 protein interferes with a body's natural "braking" system needed to neutralize stress on the heart and has shown to be markedly elevated in heart failure, particularly in HFpEF. Inhibiting PDE9 with TT-00920 restores the cardio-protective mechanism that is dysfunctional in heart failure. Compelling preclinical data demonstrates that TT-00920 strongly enhanced cardiac function and reversed ventricular remodeling in heart failure.