



## PRESS RELEASE

### **Genkyotex Announces Top-Line Results of Phase 2 Clinical Program**

#### ***Data Supports Clinical Development GKT137831 in Fibrotic Diseases***

**Geneva, Switzerland, and Archamps, France, 9<sup>th</sup> September, 2015** – Genkyotex, the leading developer of selective NOX inhibitors, announced today top-line data from its Phase 2 clinical program with GKT137831, its lead NOX1&4 inhibitor. In patients with diabetic kidney disease, GKT137831 demonstrated an excellent safety profile and statistically significant reduction in both liver enzyme and inflammatory marker levels. Treatment with GKT137831 for 12 weeks resulted in fewer adverse events than placebo, confirming its excellent safety profile. However, a reduction in albuminuria, the primary efficacy endpoint of the study, was not achieved within this timeframe.

“Our NOX1&4 development plan involves multiple fibrotic indications for GKT137831, and we are encouraged by its excellent safety profile and pharmacodynamic activity. We will continue to explore the potential of GKT137831 in fibrotic indications,” explained Dr. Ursula Ney, CEO of Genkyotex. “The data from the Phase 2 study shows a statistically significant effect on markers of liver injury and inflammation, confirming pre-clinical data obtained in multiple models of fibrotic disorders and providing the clinical foundation for the potential development of GKT137831 in the treatment of nonalcoholic steatohepatitis, systemic sclerosis and idiopathic pulmonary fibrosis. We are currently finalizing Phase 2 study designs, which we plan to begin in 2016.”

#### **About the Phase 2 Study**

Genkyotex’s multicenter, placebo-controlled, double-blind, randomized, Phase 2 trial enrolled 155 patients with diabetic kidney disease at sites in the US, Canada, Europe, and Australia (NCT02010242). The primary endpoint of the study was the change from baseline in the urine albumin-to-creatinine ratio. Predefined secondary endpoints included changes in liver enzymes, inflammatory markers including hsCRP, and triglycerides. To date, 173 individuals have been safely exposed to GKT137831.

#### **About Genkyotex**

Genkyotex is unlocking the potential of selective NOX enzyme inhibition to discover and develop a pipeline of drugs for hard to treat chronic diseases. NOX enzymes oxidize proteins, activating multiple disease pathways. Our first-in-class NOX inhibitors block this process to achieve broad therapeutic benefit in a range of prevalent and orphan diseases. For further information please visit [www.genkyotex.com](http://www.genkyotex.com) or contact:

#### **Genkyotex**

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