



PRESS RELEASE

Genkyotex's GKT137831 Granted Orphan Drug Designation in the US and EU for the Treatment of Systemic Sclerosis

Geneva, Switzerland, and Archamps, France, 11th November, 2015 – Genkyotex, the leading developer of selective NOX inhibitors, announced today that GKT137831, its lead NOX1&4 inhibitor, was granted Orphan Drug designation for the treatment of systemic sclerosis from the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The Orphan Drug designations are based on pre-clinical data obtained in multiple models of fibrotic disorders, including scleroderma. Regulators concluded that GKT137831 may be of significant benefit for patients with systemic sclerosis as studies in experimental models show that the compound may reduce the abnormal growth of connective tissue (fibrosis) and improve survival. GKT137831 has demonstrated an excellent safety profile in multiple phase 1 and phase 2 clinical studies. In a recently completed Phase 2 clinical trial, GKT137831 treatment produced a statistically significant reduction in both liver enzymes and inflammatory markers.

“Systemic sclerosis or scleroderma is one of several fibrotic diseases under evaluation with GKT137831. We believe that NOX inhibition has the potential to dampen multiple biological pathways causing the skin and internal organs of affected patients to undergo fibrosis,” explained Philippe Wiesel, MD, Executive Vice President and Chief Medical Officer at Genkyotex. “The Orphan Drug designation will allow us to accelerate the clinical assessment of GKT137831 in scleroderma, and to hopefully deliver a much needed therapeutic option for this severe, and life-threatening condition.”

Orphan Drug designation is granted to drugs or biologics that treat a rare disease or condition. In the US, this applies to diseases affecting fewer than 200,000 people, while in Europe, no more than five in 10,000. Each offers the sponsor incentives, which can include protocol assistance during clinical development, and market exclusivity post approval of 10 years in the US and seven years in the EU.

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 or contact:

Genkyotex

Elias Papatheodorou, CEO

Tel: +41 22 880 1025

Email: info@genkyotex.com

Halsin Partners

Mike Sinclair

Tel: +44 20 7318 2955

Email: msinclair@halsin.com