Archamps (France) and Geneva (Switzerland), June 27th, 2017 at 6:00pm CEST

Genkyotex Initiates Patient Enrollment into Phase 2 Trial of GKT831 in Primary Biliary Cholangitis

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX.pa), a biopharmaceutical company and the leader in NOX therapies, announced today that it has begun enrolling patients into the Company's Phase 2 clinical trial of GKT831, its NOX1 and NOX4 enzymes inhibitor, in primary biliary cholangitis (PBC). Enrollment initiation at the first investigational center in the U.S. took place following regulatory clearance by the U.S. Food & Drug Administration and local Institutional Review Board. Dosing of the first patient is expected shortly.

Genkyotex is currently working on the activation of a large network of investigational centers participating in this global trial. In total, over 50 centers are expected to be activated in the United States, Canada and several European countries. Interim top-line results from the Phase 2 clinical trial are anticipated in the first half of 2018, and full results are expected in the second half of 2018.

"*We are pleased to initiate patient recruitment for this promising clinical trial*," said Philippe Wiesel, MD, Executive Vice President and Chief Medical Officer of Genkyotex. "*Alleviating progressive liver injury and fibrosis is an important therapeutic objective in patients with active PBC. We are grateful to the global network of experienced investigators who will participate in this important Phase 2 clinical study. We are now focused on delivering trial results over the next 18 months.*"

The Phase 2 clinical trial is a 24-week, double-blind, placebo controlled, multi-center trial evaluating the safety and efficacy of GKT831 in patients with PBC and inadequate response to ursodeoxycholic acid. A total of 102 PBC patients will be enrolled in this international study and allocated to placebo or one of two doses of GKT831 (400mg once a day or 400mg twice a day). The primary objective of the trial will be to demonstrate therapeutic activity through a reduction of gamma glutamyl transpeptidade, a marker of liver injury, which also reflects oxidative stress. Secondary efficacy endpoints include markers of liver inflammation and injury (CK-18, hs-CRP, ALT), non-invasive markers of liver fibrosis (Enhanced Liver Fibrosis score, transient elastography and circulating collagen fragments).

In addition, the trial will evaluate the effect of GKT831 on bile acid metabolism, itching, autoimmunity, and quality of life. Moreover, the trial will characterize the clinical safety profile and pharmacokinetics of GKT831 in this patient population. An interim analysis will be performed once 90 patients have completed their week 6 visit.

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies. Listed on the Euronext Paris and Euronext Brussels markets, Genkyotex is established in France and, via its GenKyoTex Suisse SA subsidiary, in Switzerland. A leader in NOX therapies, its unique therapeutic approach is based on a selective inhibition of NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration.

Genkyotex's platform enables the identification of orally available small-molecules that selectively inhibit specific NOX enzymes. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, GKT831, a NOX1 and NOX4 inhibitor entered a phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) in the second quarter of 2017. This product candidate may also be active in other fibrotic indications. Its second product candidate, GKT771, is a NOX1 inhibitor targeting multiple pathways in angiogenesis, pain processing, and inflammation, and should enter a phase I clinical study at the end of 2017.

Genkyotex also has a versatile platform, Vaxiclase, that is particularly well-suited to the development of various immunotherapies. A partnership covering the use of Vaxiclase as an antigen per se (GTL003) has been established with Serum Institute of India Ltd (Serum Institute), the world's largest producer of vaccine doses. This agreement covers territories outside the United States and

Europe, and could generate up to $57 million in revenues for Genkyotex, before royalties on sales. It will enable Serum Institute to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough. The last preclinical milestone foreseen in the agreement was reached in November 2016, opening the path to formal preclinical testing prior to potential clinical development and subsequent commercialization.

For further information, please go to www.genkyotex.com.

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