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Genkyotex Announces FDA Approval of IND for Phase 2 Trial of GKT831 in Patients with Primary Biliary Cholangitis

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announced today that the U.S. Food & Drug Administration (FDA) has accepted its Investigational New Drug (IND) Application, which allows Genkyotex to proceed with a phase 2 clinical trial of GKT831, its NOX1 and NOX4 inhibitor, in patients with primary biliary cholangitis (PBC). Genkyotex expects to initiate this study prior to the end of the second quarter 2017, with interim top-line results anticipated in the first half of 2018, and full results anticipated in the second half of 2018.

A substantial proportion of patients currently receiving approved anti-cholestatic PBC therapies show sustained liver injury and progressive fibrosis. In multiple rodent models of liver disease, treatment with GKT831 achieved marked anti-inflammatory and anti-fibrotic effects, as well as statistically significant reductions in markers of liver injury and inflammation in patients with type 2 diabetes.

The planned phase 2 trial will be 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 the liver fibrosis (Enhanced Liver Fibrosis score, transient elastography and circulating collagen fragments).

"FDA clearance of our IND application is an important milestone for Genkyotex," said Elias Papatheodorou, Genkyotex's chief executive officer. "We are continuing with preparations aimed at initiating our phase 2 trial at over 50 investigational centers in North America and Europe. Demonstrating the clinical efficacy of GKT831 in fibrotic liver disease is our primary objective in this study. Importantly, the extended treatment duration and large study size will allow us to assess the effects of GKT831 on liver inflammation and fibrosis, which are important unaddressed therapeutic targets in PBC patients."

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, is expected to enter a phase II clinical trial in primary biliary cholangitis (PBC, a

fibrotic orphan disease) prior to the end of 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 is expected to enter a phase I clinical study during the second half of 2017.

Genkyotex also has a versatile platform well-suited to the development of various immunotherapies (Vaxiclase). 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, for the development by Serum Institute of cellular multivalent combination vaccines against a variety of infectious diseases. This partnership could generate up to $57 million in future revenues for Genkyotex, before royalties on sales.

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

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This press release may contain forward-looking statements by the company with respect to its objectives. Such statements are based upon the current beliefs, estimates and expectations of Genkyotex's management and are subject to risks and uncertainties such as the company's ability to implement its chosen strategy, customer market trends, changes in technologies and in the company's competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. These factors as well as other risks and uncertainties may prevent the company from achieving the objectives outlined in the press release and actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include uncertainties involved in the development of Genkyotex's products, which may not succeed, or in the delivery of Genkyotex's products marketing authorizations by the relevant regulatory authorities and, in general, any factor that could affects Genkyotex's capacity to commercialize the products it develops. No guarantee is given on forward-looking statements which are subject to a number of risks, notably those described in the registration document filed with the French Markets Authority (the AMF) on 1 April 2015 under number R.15-015, as updated in the Document E filed with the AMF on 31 January 2017 under number E.17-004, and those linked to changes in economic conditions, the financial markets, or the markets on which Genkyotex is present. Genkyotex products are currently used for clinical trials only and are not otherwise available for distribution or sale.

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