

Archamps (France), September 26, 2018 at 7:00 am CEST

Genkyotex Exceeds Patient Enrollment Target in its Phase 2 Trial with GKT831 for Primary Biliary Cholangitis

- ***Trial enrolled 111 patients, exceeding target of 102 patients***
- ***Interim results expected in early November 2018, with final results in Spring 2019***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces today the completion of enrollment in its Phase 2 trial of GKT831 in patients with Primary Biliary Cholangitis (PBC). The study enrolled a total of 111 patients in nine countries, exceeding the initial target of 102 subjects.

“The completion of enrolment in this Phase 2 trial represents a significant milestone for our GKT831 clinical program,” said Philippe Wiesel, Chief Medical Officer of Genkyotex. *“The over enrollment of the trial is indicative of the significant interest in this study from investigators. Based on the timing of enrollment completion, we expect interim results from this study in early November of this year, with final results anticipated in the Spring of 2019. We would like to thank our investigators and their staff for their invaluable contributions to this trial.”*

This Phase 2 trial is a 24-week, double-blind, placebo-controlled study, evaluating the safety and efficacy of GKT831 in patients with PBC and inadequate response to ursodeoxycholic acid (UDCA). A total of 111 PBC patients were enrolled and allocated to three treatment arms: UDCA plus placebo, UDCA plus GKT831 at 400mg once a day, and UDCA plus GKT831 at 400mg twice a day. Following the recent positive recommendation by the study’s Data Safety Monitoring Board, Genkyotex considers initiating an open-label extension for this Phase 2 trial.

GKT831 has shown potent anti-fibrotic and anti-inflammatory activity in a broad range of animal models, as well as pharmacodynamic activity in healthy subjects and diabetic patients. Mechanistic data indicate that inhibiting NOX enzymes 1 and 4 with GKT831 down regulates multiple fibrogenic pathways, including TGF- β , MCP-1 and ASK1.

“Based on the data generated to date, we believe that GKT831 has significant therapeutic potential in diseases where fibrosis plays a major role. GKT831 is currently being evaluated in two phase 2 trials, one in patients with liver fibrosis and another in patients with kidney fibrosis. Moreover, the US National Institutes of Health recently awarded a substantial grant to fund a Phase 2 trial of GKT831 in patients with idiopathic pulmonary fibrosis, further expanding the GKT831’s domains of application,” added Elias Papatheodorou, Chief Executive Officer of Genkyotex.

Genkyotex will host a conference call in English today, September 26, 2018 at 06:15 pm CEST / 12:15 pm EDT, followed by a Q&A session.

The call is accessible via the below teleconferencing information:

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Switzerland: +41 445 831 805

US: +1 646 722 49 16

UK: +44 207 194 37 59

Belgium: +32 240 358 16

Pin: 85798253#

Next financial press releases:

First-half 2018 results: today, September 26, 2018, after market

Q3 2018 business update and cash position: October 24, 2018 (after market)

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. 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 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 evaluated in a phase 2 clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and in an investigator-initiated Phase 2 clinical trial in Type 1 Diabetes and Kidney Disease (DKD). A grant from the United States National Institutes of Health (U.S. NIH) of \$8.9 million has been awarded to Professor Victor Thannickal at the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs, the core component of the program will be to conduct a Phase 2 trial with the GKT831 in patients with IPF. 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, currently undergoing preclinical testing.

Genkyotex also has a versatile platform well-suited to the development of various immunotherapies (Vaxicase). A partnership has been established with Serum Institute of India Private Ltd (Serum Institute) and could generate approximately €150 million in future revenues for Genkyotex, before royalties on sales.

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



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