Archamps (France), January 22, 2021 at 7.00 am CET

Genkyotex announces update for near term clinical development plan for setanaxib

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced clinical and governance updates.

Clinical update

Following the positive results from the Phase 1 study announced in January of 2021, which evaluated higher doses of setanaxib in healthy subjects, Genkyotex is planning to initiate a pivotal Phase 2/3 study in primary biliary cholangitis (PBC), starting in the 2nd half of 2021, with final design and protocol details subject to feedback from the US Food and Drug Administration (FDA).

In addition, the Company plans to initiate this year a Phase 2 proof-of-concept study in patients with head and neck cancer. The trial will evaluate administration of setanaxib, targeting cancer associated fibroblasts (CAFs), in conjunction with immunotherapy.

Governance

Dr. Philippe Wiesel, Executive Vice President and Chief Medical Officer of Genkyotex, has left the Company to pursue new professional projects. He will remain as a consultant by Calliditas Therapeutics.

"I would like to thank Philippe for his significant contribution to the development of Genkyotex over the past years. The Company has been a pioneer in the development of NOX therapies which, in combination with promising clinical data and regulatory progress as well as recent positive Phase 1 data, has translated into Calliditas Therapeutics showing strong commitment to the continuation of our development projects. Given the sound clinical data obtained to date with setanaxib, we are in a very strong position to create further value through a pivotal trial in PBC that is expected to start in the 2nd half of this year", **said Elias Papatheodorou, CEO of Genkyotex.**

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its unique platform enables the identification of orally available small-molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, setanaxib (GKT831), a NOX1 and NOX4 inhibitor has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic

orphan disease). Based on its positive Phase II results, a phase 3 trial with setanaxib in PBC is being planned. Setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD). A grant from the United States National Institutes of Health (NIH) of $8.9 million was 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 this program is a Phase 2 trial with setanaxib in patients suffering from IPF for which the first patient has been enrolled in September 2020. This product candidate may also be active in other fibrotic indications.

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 Private 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.

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

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CONTACTS

GENKYOTEX
Alexandre Grassin
CFO
Tel.: +33 (0)5 61 28 70 60
investors@genkyotex.com

NewCap
Dušan Orešanský
Tel.: +33 1 44 71 94 92
genkyotex@newcap.eu

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