Archamps (France), June 18, 2020 at 7.00 am CEST

Genkyotex provides new clinical data from the PBC Phase 2 trial providing further evidence of the anti-fibrotic activity of setanaxib

- ***Setanaxib improved markers of collagen turnover indicating reduced collagen synthesis and enhanced collagen degradation in patients with advanced liver fibrosis***
- ***These results provide further mechanistic insights for the anti-fibrotic activity of setanaxib and explain the rapid reduction in liver stiffness already reported in these high-risk patients***
- ***Genkyotex will submit this new data for presentation at major international liver conferences***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced the presentation of additional data from the Phase 2 trial of setanaxib in primary biliary cholangitis (PBC).

These latest results show that in patients with elevated liver stiffness (≥9.6 kPa corresponding to the histological fibrosis stage ≥ F3), setanaxib reduced type III collagen formation and induced type III collagen degradation, resulting in a net reduction of collagen accumulation. Collagen III is the main collagen type secreted by activated myofibroblasts.

As a reminder, the key finding of the PBC Phase 2 trial (see press releases from June 24 and July 25, 2019) was the rapid reduction in liver stiffness (-20.9% for setanaxib vs +4% for placebo, $p<0.05$) in patients with elevated liver stiffness (≥ 9.6 kPa), i.e. those with advanced liver fibrosis.

Fibrosis progression is primarily caused by increased collagen III formation (measured by PRO-C3, the pro-peptide of type III collagen) and insufficient collagen III degradation (measured by C3M). The latest results show that in the Phase 2 PBC trial, patients with elevated liver stiffness at baseline had increased PRO-C3 levels and PRO-C3/C3M ratios. After 24 weeks of treatment, setanaxib reduced PRO-C3 (collagen III formation), increased C3M (collagen III degradation) levels, and reduced the PRO-C3/C3M ratio indicating reduced collagen III net accumulation. Setanaxib also increased serum levels of C4M ($p<0.05$), a marker of type IV collagen degradation.

Genkyotex will submit this new data for presentation at key international liver conferences.

"These results provide further evidence of the anti-fibrotic activity of setanaxib and can explain the marked and rapid reduction in liver stiffness observed in our successful Phase 2 PBC trial. Targeting liver fibrosis is a key therapeutic objective in PBC because advanced liver fibrosis predicts adverse outcomes even in patients who achieve a biochemical response following treatment with anticholestatic agents [1] *. Importantly, this new data corroborates our intention to include patients with elevated liver stiffness in an upcoming pivotal Phase 3 trial with setanaxib"*, **said Philippe Wiesel, M.D., Executive Vice President and Chief Medical Officer at Genkyotex.**

[1] Murillo Perz CF et al. Fibrosis stage is an independent predictor of outcome in primary biliary cholangitis despite biochemical treatment response. Aliment Pharmacol Ther. 2019;50:1127–1136.

Serum collagen biomarker levels by liver stiffness stage. Values are median (ng/ml) (Q1, Q3)

	Liver stiffness <9.6 kPa	Liver stiffness ≥9.6 kPa	All patients
PRO-C3	**14.6** (12.5, 20.1)	**22.2** (15.8, 32.3)	**17.6** (13.2, 24)
PRO-C5	**1090.8** (629.5, 1467.1)	**1061.1** (636.9, 1432.2)	**1090.8** (636.9, 1432.2)
C3M	**15.8** (12.5, 18.3)	**16.3** (14.0, 21.6)	**16.1** (13.5, 20.5)
C4M	**54.5** (41.6, 66.4)	**55.6** (42.0, 71.4)	**54.5** (41.8, 67.8)
BGM	**16.6** (13.0, 21.9)	**17.3** (13.4, 20.6)	**16.8** (13.3, 21.0)
PRO-C3/C3M	**1.1** (0.8, 1.3)	**1.3** (0.8, 1.6)	**1.2** (0.8, 1.5)

Changes in serum collagen biomarker levels from Baseline to end of treatment. Values are median (ng/ml) (Q1, Q3)

	Placebo	Setanaxib 400 mg/day	Setanaxib 800 mg/day
PRO-C3	**0.2** (-14.3, 26.4)	**-9.1** (-18.9, 2.5)	**-11.4** (-16.4, 8.1)
PRO-C5	**-2.2** (-15.9, 1.9)	**-3.8** (-15.3, 15.0)	**0.0** (-7.7, 5.4)
C3M	**-4.1** (-15.0, 12.0)	**-6.9** (-14.1, 14.4)	**13.9** (-10.7, 40.6)
C4M	**0.1** (-12.7, 2.2)	**-4.1** (-14.1, 8.6)	**5.3*** (-7.5, 29.1)
BGM	**0.0** (-14.0, 14.7)	**-3.9** (-11.7, 14.9)	**1.8** (-11.2, 24.1)
PRO-C3/C3M	**-0.1** (-15.7, 19.5)	**3.3** (-20.5, 11.2)	**-22.2*** (-31.3, -5.1)

* *P* value <0.05 (800 mg/day vs placebo)

About the PCB Phase 2 trial with setanaxib

The PBC Phase 2 trial completed in 2019 was a large double blind, placebo-controlled trial conducted in patients with inadequate response to ursodeoxycholic acid (UDCA). A total of 111 patients were allocated to setanaxib 400 or 800 mg/day or placebo treatment for 24 weeks, in addition to continued UDCA treatment at a stable dose. The 800 mg/day dose was shown to have greater efficacy and was well tolerated. A key finding was the rapid mean reduction in liver stiffness (-20.9% for setanaxib vs +4% for placebo, $p<0.05$) in patients with elevated liver stiffness (≥9.6 kPa as measured by Fibroscan©), which is an excellent surrogate marker of advanced liver fibrosis (Fibrosis stage ≥F3), such patients being at particularly high risk of developing adverse disease outcomes. In these patients with elevated liver stiffness, setanaxib also achieved greater reductions in markers of cholestasis (GGT, ALP) and inflammation (hsCRP) and in additional markers of fibrosis (APRI, FIB-4).

Next financial press release:

Q2 2020 business update and cash position: July 23, 2020 (after market)

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 2 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 with IPF scheduled to recruit patients in the course of 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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