Archamps (France), December 8, 2020 at 7.00 am CET

Genkyotex's setanaxib granted Orphan Drug Designation by the European Commission for the treatment of PBC

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and leader in NOX therapies, today announced that its lead drug candidate, setanaxib, has been granted orphan drug designation (ODD) by the European Commission for the treatment of primary biliary cholangitis (PBC), following the positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

Elias Papatheodorou, CEO of Genkyotex, comments: *"This European ODD granted to setanaxib is further evidence of the acute need for new treatments in PBC. Given the recent ODD in the same indication by the US FDA, and the ODD in another fibrotic disease - idiopathic pulmonary fibrosis and systemic sclerosis - we now have a set of significant advantages for the next development phases of setanaxib in several fibrotic disorders."*

Orphan Drug Designation is granted to drugs or biological products intended for the safe and effective treatment of rare diseases with an unmet medical need, whose prevalence does not exceed 5 out of 10,000 people in the European Union. ODD in the EU provides companies with certain benefits and incentives, including clinical protocol assistance, reduced EU regulatory filing fees, access to a centralized marketing authorization procedure valid in all EU Member States and ten-year market exclusivity after obtaining marketing approval in the EU. The company is currently discussing its registration strategy for setanaxib in PBC with the FDA and the EMA.

As a reminder, Genkyotex is currently the subject of a friendly takeover bid initiated by Calliditas Therapeutics AB, a Swedish specialty pharmaceutical company focused on identifying, developing and marketing novel treatments in orphan indications with an initial focus on renal and hepatic diseases with significant unmet medical needs.

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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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 universal registration document filed with the AMF on April 30, 2020 under number D.20-0434, 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.