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Preclinical Efficacy of Genkyotex's GKT831 in Prostate Cancer Presented at ESUR18 Meeting

- ***Data Demonstrate Potential of GKT831 to Efficiently Target Cancer Associated Fibroblasts***
- ***Interim results of the Phase 2 Trial with GKT831 in Primary Biliary Cholangitis expected in early November 2018***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announced today the presentation of preclinical data showing that GKT831, the Company's clinical stage NOX1 and NOX4 inhibitor, efficiently targeted cancer associated fibroblasts (CAFs) in prostate cancer and abrogated the pro-tumorigenic influence of the tumor micro-environment. The results were presented by Dr. Natalie Sampson, Division of Experimental Urology, Dept. of Urology, Medical University of Innsbruck, Austria, at ESUR18 – the 25th Meeting of the European Association of Urology, taking place October 4-6, 2018, in Athens, Greece (ESUR18, October 5, Poster #P-23).

CAFs are an essential component of the tumor-associated stromal microenvironment, which is a primary driver of prostate cancer progression. The new preclinical data demonstrated that elevated NOX4 expression in prostate cancer correlates with disease relapse and shortened disease-free survival. Furthermore, NOX4 inhibition with GKT831 reverts primary prostate CAFs to a benign-like phenotype and abrogates their paracrine-mediated pro-tumorigenic effects on prostate cancer cells in vitro & ex vivo. Additional recent data suggest that specific CAF subtypes may have distinct tumor promoting roles. In this study, a dominant NOX4-expressing CAF subtype was identified. In these NOX4 expressing CAFs, GKT831 reduced the production of reactive oxygen species and suppressed CAF activation markers. GKT831 also blocked the onco-supportive effects of CAFs, including prostate cancer cell proliferation and migration.

"These new data further support our previous findings that NOX4 in the tumor microenvironment/CAFs plays a key role in driving progression towards aggressive prostate cancer. In addition, the results of this preclinical study are indicative of the therapeutic potential of GKT831 in targeting NOX4 in prostate cancer" said Dr. Sampson.

"Together with previously published results, these studies indicate that GKT831 has the potential to block the multiple tumor promoting effects of CAFs, including tumor growth, invasion and resistance to immunology therapies. Accordingly, we continue to evaluate potential clinical development strategies with GKT831 in order to address significant unmet medical needs in cancer patients" said Philippe Wiesel, M.D., Executive Vice President and Chief Medical Officer of Genkyotex.

The role of NOX4 in the activation of CAFs is similar to its function in the activation of myofibroblasts, a key characteristic of fibrogenesis in many fibrotic diseases. GKT831 has also demonstrated potent anti-fibrotic activity in multiple preclinical models of liver, lung, skin, and renal fibrosis. The safety and efficacy of GKT831 is currently being assessed in two separate Phase 2 trials in patients with primary biliary cholangitis (PBC) and diabetic kidney disease, two progressive fibrotic disorders. As previously announced, the interim results from the PBC study are expected in early November 2018 and the final results should be available in Spring 2019. A third phase 2 trial, funded by the US National Institutes of Health, in patients with idiopathic pulmonary fibrosis, is expected to be initiated in H1 2019.

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. Genkyotex's 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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