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Genkyotex Announces Award of Grant from Cancer Research UK to Academic Partner to Further Develop NOX Research in Oncology

Professor Gareth Thomas of Southampton University Awarded Second Grant from Cancer Research UK for Further Evaluation of GKT831 in Oncology

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announced today that Professor Gareth Thomas of the University of Southampton, United Kingdom (UK), was awarded a Biotherapeutics Drug Discovery Project grant by Cancer Research UK (CRUK), a leading cancer research and awareness organization based in the UK, to conduct a research program focused on the role of NOX inhibition in oncology. The £260 thousand grant will support the research program entitled "Combination immunotherapy for breast cancer: targeting cancer-associated fibroblasts to improving therapeutic vaccination." This is the second grant provided by CRUK to Professor Thomas for the evaluation of NOX inhibitors in oncology.

"We congratulate Professor Thomas and his team for this important achievement, which validates their initial work in elucidating the role of NOX enzymes as an important driver of resistance to immunotherapy," said Philippe Wiesel, M.D., Executive Vice President and Chief Medical Officer of Genkyotex. "This most recent grant will fund further research and inform potential clinical development strategies in oncology for our Phase 2 product candidate GKT831."

The fibrotic tumor micro-environment effectively shields cancer cells from infiltrating cytotoxic T-cells raised by immunotherapies. Previous findings by Professor Thomas have shown that GKT831 effectively deactivates cancer associated fibroblasts (CAFs), the main cellular source of the extracellular matrix which constitutes the fibrotic tumor micro-environment. These data suggest that adjuvant therapy with GKT831 has the potential to restore response to several types of immunotherapy, including vaccination and checkpoint inhibitors^{1/2}.

"We continue to believe that GKT831 has broad potential as an effective adjunctive treatment across oncology, including in breast cancer," said **Professor Thomas**. "We look forward to conducting this research program in breast cancer and are grateful for the further support from CRUK."

GKT831 has shown potent anti-inflammatory and anti-fibrotic activity in multiple preclinical models of fibrotic disorders and is currently being evaluated in patients with liver fibrosis (Phase 2 trial in primary biliary cholangitis (PBC)) and kidney fibrosis (investigator initiated Phase 2 trial in diabetic kidney disease fully funded by the Australian Juvenile Diabetes Research Foundation). A third Phase 2 trial in patients with lung fibrosis is expected to be initiated in the first half of 2019 (investigator initiated trial in idiopathic pulmonary fibrosis fully funded by the U.S. National Institutes of Health).

In November 2018, Genkyotex announced that its ongoing phase 2 trial in PBC had met the primary and secondary interim efficacy endpoints. To date, all patients have completed at least 18 weeks of treatment

and over 80% have completed the full 24-week treatment period and no cases of treatment interruptions or patient discontinuations related to pruritus have been reported. These results provide a clear clinical proof-of-concept for GKT831 and support its further clinical evaluation in multiple indications, including cancer. Final results of the Phase 2 PBC study are anticipated in the spring of 2019, as planned.

References:

- 1. Hanley CJ et al. Targeting the Myofibroblastic Cancer-Associated Fibroblast Phenotype Through Inhibition of NOX4.J Natl Cancer Inst. 2018 Jan 1;110(1). doi: 10.1093/jnci/djx121.
- 2. Sampson Net al. Inhibition of Nox4-dependent ROS signaling attenuates prostate fibroblast activation and abrogates stromal-mediated protumorigenic interactions. Int J Cancer. 2018 Jul 15;143(2):383-395. doi: 10.1002/ijc.31316.

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 orally 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 (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 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 (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. This partnership 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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