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THE WHO RECOGNIZES NOX INHIBITORS AS NEW THERAPEUTIC CLASS AND APPROVES SETANAXIB FOR GKT831

- ***World Health Organization (WHO) recognized GKT831 as first representative of NOX inhibitor therapeutic class***
- ***The recommended new stem "naxib" recognizes NOX inhibitors as a new therapeutic class***
- ***The NOX inhibitor therapeutic class has significant potential in fibrotic, inflammatory, neurodegenerative, and oncology disorders***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX) a biopharmaceutical company and the leader in NOX therapies, today announced that the World Health Organization (WHO) has recommended setanaxib as the international nonproprietary name (INN) for GKT831.

The new stem "naxib" approved by WHO refers to **NA**DPH o**x**idase inh**ib**itors, and formally establishes a new therapeutic class under the WHO INN system.

The WHO assigns an INN to new pharmaceutical substances or active pharmaceutical ingredients (API). Each INN includes a stem which indicates that a pharmaceutical product belongs to a group of substances having similar pharmacological activity, and a new stem is only recommended when a group of at least several new substances shows a confirmed novel mode of action.

Elias Papatheodorou, CEO of Genkyotex, commented: "As the leader in the development of NOX therapeutics, we are thrilled with the WHO decision to formalize NOX inhibitors as a novel therapeutic class. By recommending the INN setanaxib for GKT831, the most advanced compound in the NOX inhibitor class, the WHO is recognizing its novel mechanism of action."

NOX inhibitors have a significant therapeutic potential for fibrotic and inflammatory disorders, neurodegenerative diseases, and oncology. Recently, GKT831 has shown clinical evidence of anti-inflammatory and anti-fibrotic activity in patients with fibrotic liver disease in a Phase 2 Primary Biliary Cholangitis (PBC) trial, highlighting its potential as a possible treatment for multiple complex and difficult to treat fibrotic disorders, including non-alcoholic steatohepatitis (NASH), PBC, diabetic kidney disease (DKD), and idiopathic pulmonary fibrosis (IPF).

A second Phase 2 study is ongoing in diabetic patients with kidney fibrosis, and the US Food and Drug Administration (FDA) recently approved the initiation of an additional Phase 2 trial in patients with patients with IPF.

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, 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) and Genkyotex is planning to initiate a Phase III clinical trial in PBC following its positive Phase II results. GKT831 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 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 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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Media relations
Sophie Baumont
LifeSci Advisors
+33 6 2774 74 49
sophie@lifesciadvisors.com

Investor relations
Brian Ritchie
LifeSci Advisors, LCC
+1 212 915 2578
britchie@lifesciadvisors.com