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Sihuan Pharma gets clinical trial approval from NMPA

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Sihuan Pharmaceutical Holdings Group Ltd., the largest cardio-cerebral vascular drug manufacturer in China's prescription drug market, announced the third generation of EGFR inhibitor XZP-5809, a Category 1 innovative drug developed by the Group, has been granted drug clinical trial approval by the National Medical Products Administration (NMPA) of the PRC. The New Drug is a Category 1 innovative drug of the PRC developed by the Group.

The New Drug is a novel third-generation epithelial growth factor receptor-tyrosine kinase inhibitor ("EGFR-TKI") that has strong targeting capability, and can be taken orally. It features innovative structure, established mechanism and irreversible binding to EGFR. The New Drug has better selection with higher activity against gene-mutation EGFR and lower activity against wild-type EGFR.

Compared with products of the same type, the New Drug has distinct advantages in its activity and safety, based on the data collected from the completed preclinical trial. The New Drug and its metabolite have demonstrated lower activity against wild-type EGFR. With its better safety profile and global competitive advantage, the New Drug will be considered as a new treatment option for cancer patients.

Dr. Che Fengsheng, Chairman and CEO of Sihuan Pharmaceutical, said, "Significant progress has been made in the field of lung cancer treatment, including anti-cancer immunotherapy, but targeted therapy is still considered the best choice for non-small cell lung cancer ('NSCLC') with EGFR mutation."

The preclinical pharmacodynamic data and toxicological data indicate that the New Drug has the following characteristics: good efficacy against EGFR sensitive mutations (exon 19 deletion and L858R mutation) and against acquired resistance mutations (T790M mutation); potential clinical efficacy for patients with lung cancer brain metastasis; better safety profile and less impact on cardiac function when compared with drugs of the same type on the market. The clinical indication for the New Drug candidate is potential to be solid tumors such as locally advanced or metastatic lung cancer with EGFR-sensitive mutations (exon 19 deletion and L858R mutation) and acquired resistance mutations (T790M mutation).

Dr. Che stated, "The Group is committed to the fundamental research of innovative drugs, and finally obtains the clinical trial approval of the New Drug by overcoming the technical difficulties encountered. The obtained clinical trial approval for the New Drug will further enrich the Group's product line layout in innovative drugs. In addition to the New Drug, the Group currently has Janagliflozin, an innovative drug in the field of anti-diabetes and a number of small molecule targeted innovative drugs such as Birociclib in the field of anti-tumor are in clinical trials and are making progress well. The layout of innovative drugs in various therapeutic fields has established a solid foundation for the Group's research and development platform of innovative drugs."

Lung cancer is one of the malignant tumors with the highest morbidity and mortality in the world. In 2018, the number of cases of lung cancer around the world was 2.093 million. According to the cancer report statistics of the PRC, in terms of the number of cases, lung cancer ranks the first in the incidence of malignant tumors with approximately 781 thousand as the annual incidence cases number. According to the World Health Organization's forecast, the number of lung cancer deaths in the PRC will exceed 1 million each year by 2025.