BioSpectrum the business of Bio & Health Sciences ASIA EDITION

# NMPA approves Sinovant's clinical trial application for Derazantinib

30 April 2019 | News

**Derazantinib is an oral pan-FGFR inhibitor being developed as a potential treatment for iCCA and other tumor types with high rates of FGFR mutation.**


Sinovant Sciences has announced that its Clinical Trial Application (CTA) for derazantinib has been accepted by the Center for Drug Evaluation at the China National Medical Products Administration (NMPA), enabling the initiation of a registrational clinical trial in patients with second-line intrahepatic cholangiocarcinoma (iCCA) in the second half of 2019.

"iCCA is one of the greatest unmet needs in oncology, particularly in China," said Dr. Rae Yuan, President of Sinovant. "Patients in the second-line setting are poorly served by existing treatment options, none of which meaningfully extend survival or reduce disease burden. Derazantinib has the potential to be the first approved treatment in China for this devastating disease state, and we look forward to begin enrolling patients in our registrational program later this year."

Derazantinib is an oral pan-FGFR (fibroblast growth factor receptor) inhibitor being developed as a potential treatment for iCCA and other tumor types with high rates of FGFR mutation. The People's Republic of China has one of the world's highest incidence rates of iCCA.

"We are very pleased by the approval of this CTA, which brings Sinovant a step closer to delivering derazantinib to Chinese patients," said Dr. Xinan Chen, Executive Chairman of Sinovant. "Sinovant's advancement of derazantinib for patients with iCCA underscores our commitment to addressing major public health priorities in China."

Derazantinib is a potent, orally administered inhibitor of the fibroblast growth factor receptor (FGFR) family, a key driver of cell proliferation, differentiation, and migration. In a Phase 1/2 study in patients with iCCA harboring FGFR2 gene fusions, treatment with derazantinib resulted in an objective response rate of 21%, nearly 3 times higher than standard-of-care chemotherapy. Sinovant's partner Basilea is conducting a similar global registrational study of derazantinib in American and European patients with FGFR2 fusion-positive second-line iCCA.

Sinovant is a Chinese biopharmaceutical company dedicated to conducting globally innovative biomedical R&D in China to meet the needs of patients in Greater China and around the world. Sinovant's mission is to develop and commercialize new

medicines that address the most pressing public health challenges in China while simultaneously advancing Chinese biopharmaceutical research abroad.