BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Chi-Med to stop pancreatic cancer trial upon early success

21 January 2020 | News

Chi-Med Announces that Surufatinib Phase III SANET-p Study Has Already Achieved its Primary Endpoint in Advanced Pancreatic Neuroendocrine Tumors in China and Will Stop Early

Hutchison China MediTech has announced that the independent Data Monitoring Committee ("IDMC") of the Phase III pivotal study of **s**urufatinib in **a**dvanced **n**euro**e**ndocrine **t**umors – **p**ancreatic ("SANET-p") has completed a pre-planned interim analysis. The IDMC recommended that the study stops early as the pre-defined primary endpoint of progression free survival ("PFS") had already been met.

Following the early success of this study, Chi-Med now plans to arrange a pre-New Drug Application ("NDA") meeting with the China National Medical Products Administration ("NMPA") to discuss the preparation of the NDA for surufatinib for this indication. Chi-Med intends to submit the results of the SANET-p study for presentation at an upcoming scientific conference.

Christian Hogg, Chief Executive Officer of Chi-Med, said, "This positive data is a further important milestone for Chi-Med. Following surufatinib's NDA submission for the treatment of non-pancreatic neuroendocrine tumors, these positive results for pancreatic neuroendocrine tumors reinforce that surufatinib has the unique opportunity to address all advanced neuroendocrine tumors. We believe that no targeted therapies are approved in China or globally for such a broad spectrum of neuroendocrine tumor disease."

In November 2019, the U.S. Food and Drug Administration ("FDA") granted Orphan Drug designation to surufatinib for the treatment of pancreatic neuroendocrine tumors. The China NDA for surufatinib for the treatment of advanced non-pancreatic neuroendocrine tumors was accepted for review by the NMPA, and was subsequently granted Priority Review status in December. Currently Chi-Med is building an oncology-focused sales and marketing team to launch surufatinib if approved in China.

About SANET-p

SANET-p is a Phase III study in China of surufatinib in patients with low-grade or intermediate-grade advanced pancreatic neuroendocrine tumor patients for whom there is no effective therapy. In this study, patients are randomized at a 2:1 ratio to

receive either 300 mg of surufatinib orally daily or placebo, on a 28-day treatment cycle. The primary endpoint of the study is to evaluate the PFS, with secondary endpoints including objective response rate (ORR), disease control rate (DCR), time to response (TTR), duration of response (DoR), overall survival (OS), safety, and tolerability. Additional details may be found at clinicaltrials.gov, using identifier NCT02589821.