Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Chi-Med announces initiation of Phase III sulfatinib registration trial in patients with NETs in China

Published on December 18, 2015 at 6:50 AM

Hutchison China MediTech Limited ("Chi-Med") (AIM: HCM) today announces that Hutchison MediPharma Limited ("HMP"), its drug R&D subsidiary, has initiated SANET-ep**,** a Phase III sulfatinib (HMPL-012) registration trial in China in patients with extra-pancreatic neuroendocrine tumors ("NETs"), which are all non-pancreatic NETs, including, for example, NETs originating in the lymph, lung and across the gastrointestinal tract. Preparations and site selection had begun in the middle of this year and the first patient was dosed on December 17, 2015.

SANET-ep is a randomized, double-blind, placebo-controlled, multi-center Phase III sulfatinib registration study to treat pathologically low or intermediate grade NET patients whose disease has progressed, locally advanced or distant metastasized and for whom there is no effective therapy. Patients will be randomized at a 2:1 ratio to receive either 300 milligrams of sulfatinib orally once per day, or placebo, on every 28-day treatment cycle. The primary objective of this study is to evaluate the progression-free survival of sulfatinib as compared to that of placebo, with secondary endpoints including objective response rate ("ORR"), disease control rate, time to response, duration of response, overall survival, safety and tolerability. Approximately 270 patients will be enrolled in the SANET-ep study from more than 20 centers across China, with top-line results expected in 2018.

Additionally, the second Phase III sulfatinib registration trial, SANET-p, in pancreatic NET patients, is expected to be initiated imminently in China. SANET-p employs a similar treatment regimen and has primary and secondary endpoints similar to those for SANET-ep trial. Approximately 195 patients will be enrolled in SANET-p and is expected to start by the end of 2015, with top-line results expected in 2017.

Sulfatinib is an oral drug candidate that demonstrates dual inhibition of the tyrosine kinase activity associated with vascular endothelial growth factor receptor ("VEGFR") and fibroblast growth factor receptor ("FGFR") 1, a receptor kinase which also plays a role in tumor angiogenesis. In 2014, HMP completed the first-in-human Phase I clinical trial of sulfatinib in China; the detailed results were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in early November 2015 *(http://www.chi-med.com/sulfatinib-ph1-eortc-2015/)*. The Phase I clinical data indicates that sulfatinib has the highest ORR reported to date in NET patients. An ORR of 44% was observed for sulfatinib in 18 evaluable patients, compared to less than 10% for sunitinib and everolimus, the two approved targeted therapies for pancreatic NET patients.

In October 2014, HMP initiated a multi-center, single-arm, open-label Phase Ib/II study in NET patients in China to further evaluate the efficacy, safety, tolerability and pharmacokinetic characteristics of sulfatinib. This study, projected to enroll approximately 80 patients, is near to completion of patient enrolment.

Furthermore, the Phase I and Phase Ib/II studies in China provide a guide for the selection of the recommended starting dose for the Phase I study in patients with advanced solid tumors in the United States, which had the first patient enrolled in early November 2015.

In addition to these four NET studies, HMP also plans to initiate a Phase Ib study in China to evaluate the safety, pharmacokinetics and efficacy of sulfatinib in patients with both medullary and differentiated thyroid cancer by the end of 2015.

Source:
Hutchison China MediTech
