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CStone completes VOYAGER trial enrollment in Chinese patients

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The study was designed to evaluate the safety and efficacy of avapritinib as a third- or fourth-line treatment for patients with advanced gastrointestinal stromal tumors (GIST)

CStone Pharmaceuticals has announced that the on-going, global Phase III VOYAGER clinical trial of avapritinib, an investigational drug discovered by CStone's partner, Blueprint Medicines, has completed target patient enrollment in China. In addition, the VOYAGER trial's enrollment target has been reached globally. The study was designed to evaluate the safety and efficacy of avapritinib as a third- or fourth-line treatment for patients with advanced gastrointestinal stromal tumors (GIST), in comparison with that of regorafenib, the current standard-of-care treatment for third-line GIST. On July 10, 2019, CStone announced the dosing of the first patient in China for the VOYAGER trial.

Blueprint Medicines expects to report top-line VOYAGER trial data in the second quarter of 2020. In August 2019, the U.S. Food & Drug Administration (FDA) accepted Blueprint Medicines' New Drug Application (NDA) for avapritinib for the treatment of adult patients with PDGFRA Exon 18 mutant GIST, regardless of prior therapy, and fourth-line GIST. Subject to an initial approval of avapritinib, Blueprint Medicines plans to submit a supplemental NDA to the U.S. FDA for avapritinib for third-line GIST in the second half of 2020. CStone plans to submit an NDA for the treatment of third-line GIST to the China National Medical Products Administration (NMPA) in the second half of 2020.

GIST is the most common mesenchymal tumor of the GI tract, and it is most prevalent in patients aged 50 to 80. Around 90% of all GIST cases are associated with dysregulated cell growth due to mutations in KIT and PDGFRA tyrosine kinases. Existing data on regorafenib, the current standard third-line GIST treatment, shows a median progression-free survival of 4.8 months and an objective response rate (ORR) of only about 5%. There is currently no approved treatment for GIST patients who have failed third-line treatment. Thus, there are high unmet clinical needs in patients with third-line and later GIST.

Avapritinib is an investigational, orally available, potent and highly selective inhibitor of KIT and PDGFRA. Clinical data on avapritinib have demonstrated encouraging anti-tumor activity and benign tolerability in patients with PDGFRA Exon 18 mutants (primarily includes patients with the D842V mutation) and fourth-line GIST, two patient populations currently lacking effective therapies.

“We are pleased that in China, the global Phase III VOYAGER trial has completed its enrollment target sooner than planned, and this rapid progress reaffirms the urgent clinical needs of GIST patients in China,” said Dr. Frank Jiang, Chairman and CEO of CStone. “With the appointment of Ms. Shirley Zhao, a seasoned pharmaceutical executive who has led the

successful launches of numerous major brands, to the position of General Manager for Greater China and Head of Commercial, we are more confident than ever in our ability to accelerate CStone's transition toward a commercial-stage company and to potentially bring avapritinib and other key assets to the China market.”