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CStone announces first patient dosed in China with avapritinib for advanced GIST

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Global Phase III clinical trial to evaluate the safety and efficacy of avapritinib as a 3rd or 4th line treatment for patients with gastrointestinal stromal tumours (GIST), in comparison with regorafenib

CStone Pharmaceuticals, on 9 July 2019, announced in Suzhou, China that the first patient has been dosed in China with avapritinib in the ongoing global Phase III VOYAGER clinical trial. This study is designed to evaluate the safety and efficacy of avapritinib as a third-line or fourth-line treatment for patients with gastrointestinal stromal tumours (GIST), in comparison with that of regorafenib, the current standard of care treatment for GIST. To be eligible, patients must have been previously treated with imatinib and one or two additional tyrosine kinase inhibitors. The trial's primary efficacy endpoint is progression-free survival (PFS).

Avapritinib, an orally available, potent and highly selective inhibitor of KIT and PDGFRA, was discovered by CStone's partner Blueprint Medicines. Approximately 90% of GIST cases are associated with mutations of KIT and PDGFRA tyrosine kinases, leading to dysregulation of cell growth. Previously published preclinical results have shown that avapritinib can potently treat GIST associated with KIT and PDGFRA mutations.

Clinical data from the ongoing Phase I NAVIGATOR study presented in June 2019 demonstrated encouraging anti-tumour activity and favourable tolerability in patients with PDGFRA Exon 18 mutant and fourth-line GIST, two populations with no effective therapies. Blueprint Medicines has recently submitted a New Drug Application (NDA) to the U.S. FDA for these indications.

As of the data cutoff date of November 16, 2018:

- In 43 evaluable patients with PDGFRA Exon 18 mutant GIST (including 38 patients with PDGFR? D842V-driven GIST), the ORR was 86% and the median duration of response was not reached.

- In 111 evaluable patients with fourth-line GIST, the ORR was 22% and the median duration of response was 10.2 months.
- Avapritinib had a favourable safety profile, with most adverse events determined by investigators to be Grade 1 or 2 as of the data cutoff date.

Dr Frank Jiang, Chairman and CEO of CStone, commented: "Development of precision therapy in oncology is one of CStone's core strategies. GIST is a rare disease, and avapritinib has demonstrated its efficacy in treating GIST patients with tumour mutations resistant to currently available therapies. Our partner Blueprint Medicines has submitted the NDA for avapritinib to the U.S. FDA, and the agent is expected to be CStone's second product that gets approved in the U.S. As we continue to make progress with the VOYAGER trial in China, we hope that the clinical data can soon support the approval of avapritinib in the country, and ultimately allow the product to benefit patients with advanced GIST who now lack effective treatments."

CStone's Chief Medical Officer Dr Jason Yang noted: "We are pleased that the first Chinese patient has been enrolled and dosed in this Phase III trial of avapritinib as a third-line agent for advanced GIST. We will do our best to have more Chinese centres participate in this important global clinical study."