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CStone announces first patient dosed in China with BLU-667

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Part of the ongoing, global Phase I ARROW trial that is designed to evaluate the overall response rate (ORR), duration of response, pharmacokinetics, pharmacodynamics and safety of BLU-667 in patients with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC) and other advanced solid tumors

CStone Pharmaceuticals, on 13 August 2019, announced the dosing of the first patient in China for the Phase I registrational study of BLU-667, which was discovered by the company's partner Blueprint Medicines. This clinical trial is a part of the ongoing, global Phase I ARROW trial that is designed to evaluate the overall response rate (ORR), duration of response, pharmacokinetics, pharmacodynamics and safety of BLU-667 in patients with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC) and other advanced solid tumours.

Among all malignant tumours, lung cancer has the highest incidence and mortality rates in the world. Due to heightened risk factors such as pollution and the prevalence of smoking in China, there are approximately 730,000 new cases of lung cancer and 610,000 lung cancer-related deaths reported in China each year. NSCLC accounts for 80-85% of all lung cancers and RET fusions occur in approximately 1-2% of all NSCLC cases. Both platinum-based chemotherapy, the standard first-line treatment for RET-fusion NSCLC, and the second-line treatment of cytotoxic drugs or immune checkpoint inhibitor-based monotherapies offer limited efficacy. As a result, patients experience significant physical and psychological burdens and a lower quality of life.

Thyroid cancer is the most common type of endocrine cancer and has shown rising incidence rates in recent years. There are approximately 90,000 new cases of thyroid cancer and 6,800 thyroid cancer-related deaths in China each year. MTC accounts for 2-5% of all thyroid cancers, and RET mutations occur in nearly all hereditary MTC patients and approximately 50% of all sporadic MTC patients. Currently, there is no effective standard of care treatment approved for MTC patients in China.

BLU-667 is an orally available, highly selective and potent RET inhibitor. In June 2018, CStone obtained exclusive rights from Blueprint Medicines to develop and commercialize three therapeutic candidates, including BLU-667, in Mainland China, Hong Kong, Macau and Taiwan. Blueprint Medicines retains development and commercial rights to the three therapeutic candidates in the rest of the world.

In June 2019, Blueprint Medicines reported updated results from the ARROW clinical trial. BLU-667 showed durable anti-tumour activity regardless of RET-altered tumour type and was well-tolerated. As of the data cutoff date of April 28, 2019:

- In 35 evaluable patients previously treated with platinum-based chemotherapy. BLU-667 demonstrated an ORR of 60% (one complete response and 20 partial responses (PR); all responses were confirmed) and a disease control rate (DCR) of 100%.
- In 16 evaluable RET-mutant MTC patients previously treated with cabozantinib or vandetanib, BLU-667 demonstrated an ORR of 63% (nine confirmed PRs, one PR pending confirmation) and a DCR of 94%.
- These patients with RET-fusion NSCLC and RET-mutant MTC received a starting dose of 400mg once daily, which is the recommended Phase 2 dose. Across all patients, BLU-667 was well-tolerated and most adverse events reported by investigators were Grade 1 or 2.

Dr Frank Jiang, Chairman and CEO of CStone, commented: "In China, lung cancer has the highest incidence rate and mortality rate among all malignancies. BLU-667 is an agent with great potential, and it could address the existing treatment gap for RET-fusion NSCLC and other RET-altered tumours in this country. I am pleased that through our dedicated efforts, we have successfully carried out the dosing of the first patient in China as a part of the ongoing, global registrational study."

"Precision medicines such as BLU-667 may be highly effective in treating genomically defined cancers and bring significant clinical benefit to patients. The global ARROW study has thus far produced promising clinical data. I am confident that with CStone's effective execution, we can efficiently accelerate this clinical trial in China so that Chinese patients with RET-altered tumours can access this therapy as soon as possible," noted Dr Jason Yang, CStone's Chief Medical Officer.