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CStone to initiate clinical development of CS1001 and BLU-554 in combination therapy for HCC

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CStone Pharmaceuticals has announced that it has received approval to initiate clinical development in China of CS1001 in combination with BLU-554 (CS3008) in patients with locally advanced or metastatic hepatocellular carcinoma (HCC). The trial is a multi-center, open-label, and multi-dose Phase Ib/II study that aims to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and anti-tumor efficacy of the combination in advanced HCC.

In 2015, there were approximately 326,000 deaths caused by liver cancer in China, making it the second leading cause of cancer death. HCC accounts for approximately 85-90% of all liver cancer cases and is the sixth most common cancer worldwide, with more than half the new cases and deaths every year occurring in China. Currently, advanced HCC represents a significant unmet need for both patients and physicians, with limited approved therapies.

CS1001 is a proprietary anti-PD-L1 monoclonal antibody developed by CStone, and one of the company's three backbone immuno-oncology products. Currently, CS1001 is being investigated for the treatment of lung cancer, gastric cancers, and other advanced malignancies. In a Phase Ia study, CS1001 was well-tolerated and demonstrated anti-tumor activity with partial responses observed in a number of tumor types.

BLU-554 is a potent and highly selective inhibitor of fibroblast growth factor receptor 4 (FGFR4) discovered by CStone's partner Blueprint Medicines. In previously presented data from an ongoing Phase I trial for the treatment of advanced HCC patients with aberrant fibroblast growth factor 19 (FGF19)-FGFR4 pathway activation, BLU-554 monotherapy was generally well-tolerated and demonstrated encouraging anti-tumor activity. The U.S. Food and Drug Administration has granted orphan drug designation to BLU-554 for the treatment of HCC.

In June 2018, CStone entered into an exclusive collaboration and license agreement with Blueprint to develop and commercialize three therapeutic candidates, including BLU-554, in mainland China, Hong Kong, Macau and Taiwan. Blueprint retains development and commercial rights to the three licensed therapeutic candidates in the rest of the world.

Dr. Frank Jiang, Chairman and CEO of CStone, commented: "One of CStone's missions is to develop novel therapies to address important unmet needs created by highly prevalent and difficult-to-treat cancers in China. Combination therapy and precision medicine are the core strategies of our pipeline. Through our partnership with Blueprint, we have already initiated a China clinical program with BLU-554 as a monotherapy for HCC earlier this year, which is part of an ongoing global study. We expect the combination of BLU-554 with CS1001 can offer an important additional treatment option for this challenging disease."

"Emerging clinical data have shown encouraging results in HCC by combining immunotherapies with targeted therapies that are active as single agents. The combination of CS1001 and BLU-554 represents a great example of such an approach and a potential first-line treatment strategy for advanced HCC with FGF19-FGFR4 activation. We will rapidly advance the clinical development of this program to further explore these two promising drug candidates in combination," noted Dr.Archie Tse, Chief Translation Medical Officer of CStone.