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CStone submits an abstract on CS1001-201 trial to 2019 ASH Annual Meeting

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The CS1001-201 trial reported in the abstract is a single-arm, multi-centre Phase II clinical study designed to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of CS1001 monotherapy in relapsed or refractory extranodal natural killer (NK)/T-cell lymphoma (rr-ENKTL).

CStone Pharmaceuticals, on 20 August 2019, announced that an abstract on the company's CS1001-201 trial has been submitted to the upcoming 2019 American Society of Hematology (ASH) Annual Meeting. This will mark the first release of CS1001-201 clinical study data since the trial began.

CS1001 is an investigational anti-PD-L1 monoclonal antibody developed by CStone. CS1001 is currently being evaluated in multiple clinical trials in China, including one multi-arm Phase I study, two registrational Phase II studies, and three Phase III clinical studies. Based on previously released data, CS1001 has shown good overall safety and tolerability and demonstrated promising clinical utility for combination therapy in various tumour types.

The CS1001-201 trial reported in the abstract is a single-arm, multi-centre Phase II clinical study designed to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of CS1001 monotherapy in relapsed or refractory extranodal natural killer (NK)/T-cell lymphoma (rr-ENKTL). The primary endpoint of the study is objective response rate (ORR).

ENKTL is a subtype of mature T-cell and NK-cell lymphoma. With its particular geographic predilection, the incidence rate of ENKTL is significantly higher in Asia than it is in Europe or North America. There are around 5,300 new ENKTL cases in China each year, which accounts for approximately 6% of all lymphoma incidences in the country. Approximately 50% of those ENKTL cases progress to rr-ENKTL. ENKTL is an aggressive malignancy with a dismal prognosis. Currently, there is no standard treatment for ENKTL patients in whom the L-asparaginase-based combination therapy has not been effective. CS1001-201 is the first clinical trial investigating an anti-PD-L1 antibody in rr-ENKTL patients, and durable anti-tumour activity has already been observed in the trial.

The abstract submitted to the 2019 ASH Annual Meeting, if accepted, will highlight the safety and efficacy data from the CS1001-201 Phase II study in rr-ENKTL patients, and it will be the first report of the CS1001-201 trial and the fourth data update on CS1001 at a major scientific conference in 2019, following the ASCO Annual Meeting, the ESMO Annual Congress, and the CSCO Annual Meeting.