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ASIA EDITION

CStone receives US FDA IND clearance to evaluate Sugemalimab Monotherapy

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Extending the Global First Anti-PD-L1 Registration Clinical Study Targets for R/R ENKTL from China to the U.S.

CStone Pharmaceuticals Co., Ltd. on 31 August 2020 announced that the US Food and Drug Administration (FDA) has completed their review of the Investigational New Drug (IND) application for anti-PD-L1 monoclonal antibody sugemalimab (CS1001) monotherapy in the relapsed or refractory extranodal natural killer (NK)/T-cell lymphoma (R/R ENKTL) with study may proceed (SMP) letter received.

Sugemalimab is an investigational fully human, full-length anti-PD-L1 monoclonal antibody developed by CStone. Compared with other drugs of the same class, sugemalimab has a lower risk of immunogenicity and potential toxicities in patients. CS1001-201 is a single-arm, multicenter pivotal Phase II clinical study designed to evaluate sugemalimab monotherapy in R/R ENKTL. The IND clearance indicates that the ongoing CS1001-201 study in China will be extended to the US.

ENKTL is a subtype of mature T cell and NK cell lymphoma. Epidemiology of the disease is characterized by higher incidence rates in Asia than in Europe or North America. In China, ENKTL accounts for approximately 6% of all lymphoma cases. R/R ENKTL is highly malignant and aggressive and has a poor prognosis. Patients with R/R ENKTL lack effective salvage treatments if standard L-asparaginase-based regimens fail, and do not respond well to traditional treatments.

Dr. Jason Yang, Chief Medical Officer of CStone**,** commented: "For the treatment of ENKTL, CR rate is a critical outcome measure. Data reported for CS1001-201 study on 2019 ASH meeting shows that sugemalimab demonstrated a CR rate of 33.3% with a durable response, an objective response rate (ORR) of 43.3%, and 1-year OS rate of 72.4%. These results represent a major breakthrough compared to current treatment options and support sugemalimab as a potential conditioning regimen for hematopoietic stem cell transplantation. We will work closely with the US FDA and the National Medical Products Administration (NMPA), to bring sugemalimab to R/R ENKTL patients worldwide soon."