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ASIA EDITION

Sintilimab injection to provide efficacy with safety profile for Extranodal NK/T Cell Lymphoma treatment

June 6, 2019 | News

ORIENT-4, the first data released globally for prospective phase II clinical study of PD-1 monoclonal antibody for the treatment of r/r ENKTL, evaluates the efficacy and safety of sintilimab



Innovent Biologics, Inc., a world-class biopharmaceutical company, presented the research data on the treatment of relapsed or refractory extranodal NK/T cell lymphoma (ORIENT-4) by sintilimab, the anti-PD-1 antibody that co-developed with Eli Lilly and Company in 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) on 5 June 2019. ORIENT-4 is the first clinical study of PD-1 antibody from China that was orally presented at ASCO.

The oral presentation of the result on the treatment of relapsed or refractory extranodal NK/T cell lymphoma (ORIENT-4) with sintilimab is presented by Prof Jianyong Li, Director of Department of Hematology of Jiangsu Province Hospital.

Extranodal NK/T cell lymphoma is an aggressive malignancy and accounts for more than 20% of the peripheral T-cell lymphoma in Asia. Currently, patients with relapse or refractory disease have few treatment options and poor prognosis. According to historical data, the overall survival is about 6 months, reflecting high unmet medical needs.

Patients receive 200 mg sintilimab every 3 weeks until disease progression. Treatment beyond disease progression is allowed. This study includes 28 patients with r/r ENKTL who have progressed after receiving an average of 3 conventional treatments. The primary endpoint is objective response rate (ORR) per LUGANO2014 criteria.

According to the predefined analysis, 19 patients achieved objective response for an ORR of 67.9%, disease control rate (DCR) of 85.7% and 1-year overall survival (OS) rate was 82.1%. (The data cutoff was February 2, 2019, with the median follow-up time of 15.4 months; at which time, 19 patients were still on treatment.)

The results of the ORIENT-4 study suggests that sintilimab, one of 17 major drugs presented at ASCO Annual Meeting and also the only drug developed outside the U.S. and commented by Biomedtracker and Datamonitor Healthcare, may provide efficacy with an acceptable safety profile for the treatment of r/r ENKTL.