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ASIA EDITION

Innovent announces preliminary results of Sintilimab at ASCO

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As the top and most influential international oncology conference, ASCO Annual Meeting provides the most important platform for publishing and discussing cutting edge clinical studies.

Innovent Biologics, a world-class biopharmaceutical company that develops and commercializes high quality medicines has announced that the preliminary results of sintilimab, the anti-PD-1 antibody that co-developed with Eli Lilly and Company, in combination with chemotherapy for 1L advanced or metastatic non-small cell lung cancer (NSCLC) (NCT02937116, cohort D and cohort E) were presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO).

As the top and most influential international oncology conference, ASCO Annual Meeting provides the most important platform for publishing and discussing cutting edge clinical studies. Under the theme "Caring for Every Patient, Learning from Every Patient", 2019 ASCO Annual Meeting has attracted numerous top oncologists, scholars, staff from regulatory and patient organizations to share the latest updates and achievements in clinical oncology, with the ultimate goal to help deliver more promising medicines and treatment options to cancer patients.

It is worth noting that more and more Chinese companies choose to participate and disclose their programs in ASCO, showcasing the importance of emerging Chinese biotech industry. As a leading Chinese biotech company, Innovent will provide key result update of several clinical studies at the ASCO 2019 Annual Meeting. The results on the treatment of relapsed or refractory extranodal NK/T cell lymphoma (ORIENT-4) with sintilimab will be presented in an oral session, and key data from six other clinical studies will be presented by posters and other sessions.

Lung cancer is one of the malignant tumors with the highest morbidity and mortality, and non-small cell lung cancer (NSCLC) accounts for approximately 80%-85% of all lung cancer cases. Cohort D and E of NCT02937116, Phase Ib study inChina, evaluating the efficacy and safety of sintilimab monotherapy or in combination with chemotherapy for patients with advanced NSCLC. Cohort D and E of NCT02937116 are designed to evaluate the efficacy and safety of sintilimab in combination with chemotherapy for 1L unresectable locally advanced or metastatic non-squamous (nsq-) and squamous (sq-) NSCLC patients. Patients with EGFR mutations or ALK rearrangements were excluded from these cohorts. Cohort D enrolled non-squamous NSCLC patients who received sintilimab in combination with pemetrexed platinum doublet. Cohort E enrolled squamous NSCLC patients who received sintilimab in combination with gemcitabine and cisplatin.

At data cutoff on 15 Jan 2019, 21 and 20 patients had been enrolled in cohort D and E, respectively. Objective response rate (ORR) in nsq- and sq-NSCLC was 68.4% (95% CI, 43.4 ~ 87.4) and 64.7% (95% CI, 38.3 ~ 85.8) respectively based on data from 19 and 17 patients with at least one radiologic efficacy assessment. Median progression free survival (mPFS) was 11.4 months (95% CI, 3.1 ~ NA) and 6.5 months (95% CI, 5.3 ~ 8.0), respectively.

The combination of sintilimab and chemotherapy showed clinical activity with an acceptable safety profile in 1L nsq- and sq-NSCLC.

Based on the results of the Phase Ib studies, Innovent and Eli Lilly have initiated two Phase III clinical trials evaluating sintilimab in combination with chemotherapy in 1L nsq- (NCT03607539) and sq-NSCLC (NCT03629925) in patients without EGFR mutations or ALK rearrangements to further investigate the efficacy of sintilimab in combination with chemotherapy for patients with advanced or metastatic NSCLC in China.

Tyvyt (sintilimab injection) is an innovative drug jointly developed in China by Innovent and Eli Lilly and Company. Innovent is also conducting clinical studies of sintilimab injection in the United States.