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## Updated Safety and Efficacy of MSB2311 (an Anti-Programmed Death-Ligand 1 Antibody) in Chinese Patients with Advanced Solid Tumors and Hematological Malignancies from a Phase 1 Study.

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**Background:** MSB2311 is a novel humanized PD-L1 antibody with a unique pH-dependent antigen binding property that enables intra-tumor recycling and potentiates tumor penetration.

**Methods:** Patients with metastatic solid tumors or selected lymphoma progressed on or after standard treatments were enrolled in this Phase I study. In dose escalation part, MSB2311 was given at dose levels of 3, 10, and 20 mg/kg intravenously every 3 weeks. At the dose expansion part, patients with enriched biomarker expression, including EBV+, PD-L1+ (TPS≥50%), MSI-High or TMB-High (≥10muts/Mb), were dosed at 20mg/kg Q3W or 10mg/kg Q2W. Primary objectives are to evaluate the safety and tolerability and to identify MTD and RP2D. Secondary objectives include the assessment of pharmacokinetic parameter, immunogenicity, and preliminary anti-cancer activity per RECIST1.1.

**Results:** As of data cutoff by Aug 31, 2020, 33 Chinese patients had been treated, including 27 heavily pre-treated solid tumor patients and 6 lymphoma patients. No dose limiting toxicity was reported and MTD has not been reached. The most common AEs (>20%) included: anemia, hypothyroidism, aspartate aminotransferase elevated, proteinuria, weight

loss. 13 patients (39.4%) experienced grade 3 AEs, and 6 patients (18.2%) experienced SAEs. No treatment related grade 4 or 5 event was reported. Of the 17 efficacy evaluable solid tumor patients with biomarker selection, 6 achieved confirmed partial response with 35% ORR: 2/8 (25%) at 10 mg/kg Q2W and 4/9 (44%) at 20 mg/kg Q3W. Additionally, one patient achieved sustained iPR via iRECIST. 4 out of 7 responding patients (including one iPR) achieved tumor shrinkage of more than 50%, 3 of them got durable response (≥24 weeks).1 out of 6 lymphoma patients achieved PR.

**Conclusions:** MSB2311 demonstrated a manageable safety profile and promising preliminary antitumor activity in patients with advanced solid tumors and selected lymphomas.

**Title:**
Updated Safety and Efficacy of MSB2311 (an Anti-Programmed Death-Ligand 1 Antibody) in Chinese Patients with Advanced Solid Tumors and Hematological Malignancies from a Phase 1 Study.

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No

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Yes

**Is this clinical trial registered?**
Yes

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No

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Yes

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No

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No

**Has this research been submitted for publication in a medical journal?**
No

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