TPS7090 Poster Session

Phase 2 study of MK-3475A in relapsed or refractory classic Hodgkin lymphoma or primary mediastinal large B-cell lymphoma.

Alejandro Berkovits, Jessica Flynn, Katherine Ryland, Rushdia Zareen Yusuf, Wojciech Jurczak; Immunocel Chile, Providencia, Chile; Merck & Co., Inc., Rahway, NJ; Maria-Sklodowska-Curie National Research Institute of Oncology, Krakow, Poland

Background: The PD-1 inhibitor pembrolizumab is approved globally for the treatment of multiple cancers, including relapsed or refractory (R/R) classic Hodgkin lymphoma (cHL) and R/R primary mediastinal large B-cell lymphoma (PMBCL). Pembrolizumab is currently administered as an intravenous infusion. Subcutaneous administration of pembrolizumab offer advantages to patients, providers, and the healthcare system. MK-3475A is pembrolizumab with berahyaluronidase alfa for subcutaneous administration (subcutaneous pembrolizumab). Berahyaluronidase alfa, a human hyaluronidase variant developed and manufactured by Alteogen Inc., is a permeation enhancer that increases dispersion and allows for subcutaneous administration of pembrolizumab in 1 injection for both Q3W and Q6W dosing. Here, we describe the methodology of a single-arm, open-label, phase 2 study (NCT06504394) designed to evaluate subcutaneous pembrolizumab in participants with R/R cHL or R/R PMBCL. **Methods:** Key eligibility criteria include participants aged ≥18 years with a histologically confirmed diagnosis of cHL or PMBCL that is FDG-avid per WHO classification criteria, radiographically measurable disease, and an ECOG performance status of 0 or 1. Participants with cHL must be anti–PD-1 naive and have not responded to or relapsed after ≥1 line of multiagent therapy, did not achieve a complete response (CR) or relapsed after autologous stem cell transplant (auto-SCT), or are ineligible for auto-SCT. Participants with PMBCL must be anti–PD-1 naive and have not responded to or relapsed after ≥2 prior lines of therapy (≥1 rituximab based), or did not achieve a CR or relapsed after auto-SCT or are ineligible for auto-SCT. Key exclusion criteria include clinically significant cardiovascular disease, pericardial effusion or clinically significant pleural effusion, or an additional malignancy that is progressing or has required active treatment within the past 2 years. Approximately 60 participants will be enrolled. All participants will receive subcutaneous pembrolizumab 790 mg every 6 weeks for up to 18 cycles (~2 years), or until disease progression or other discontinuation criteria are met. Primary end points are pharmacokinetics during cycle 1 and objective response rate per Lugano classification criteria by investigator review. Secondary end points are pharmacokinetics at steady state (cycle 3), antidrug antibody levels, safety and tolerability, and duration of response per Lugano classification criteria by investigator review. CT scans will be performed every 12 weeks; PET scans will be performed at week 12, week 24, and to confirm CR. Adverse events (AEs) will be monitored throughout the study and for ≤30 days after treatment end (90 days for serious AEs; or 30 days if new anticancer therapy is initiated) and will be graded per NCI CTCAE v5.0. Recruitment is ongoing. Clinical trial information: NCT06504394. Research Sponsor: Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.