TPS2674 **Poster Session**

Autologous tumor-infiltrating lymphocytes (HS-IT101) with low-dose lymphodepletion and IL-2 infusion for the treatment of advanced solid tumors: A phase I clinical trial.

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Background: Adoptive cell therapy with tumor-infiltrating lymphocytes (TIL-ACT) has demonstrated great therapeutic potential in numerous solid tumors and has become an effective treatment for melanoma. However, high-dose lymphodepletion chemotherapy and IL-2 infusion during the treatment could cause serious safety risks, even death. The purpose of this study is to develop a TIL cell therapy product (HS-IT101) that requires low-dose lymphodepletion and IL-2 infusion to reduce safety risks and to improve clinical accessibility. Currently, the Phase I clinical trial (NCT06342336) for the treatment of advanced solid tumors with HS-IT101 has been initiated. **Methods:** HS-IT101 is an autologous non-genetically modified TIL-ACT product independently developed by Sino-cell Biomed. The tumor tissue of culture require is ≥0.05g, and the manufacture time needed is 14 days. This study is a single-arm, multi-center, open-label Phase I clinical trial of HS-IT101 for advanced solid tumors. The plan is to enroll 20 - 44 patients to explore the safety and preliminary efficacy under low-dose lymphodepletion and IL-2 infusion. Before HS-IT101 infusion, subjects will receive lymphodepletion chemotherapy consisting of cyclophosphamide (Cy) and fludarabine (Flu) for 3 - 4 days (Cy: 900/2250mg/m^2 & Flu: 90/120mg/m^2). After HS-IT101 infusion, 1/2MIU/m^2 of IL-2 will be subcutaneously injected once a day for a maximum of 3 doses. The primary endpoint is the occurrence of adverse events (AE) and serious adverse events (SAE) after HS-IT101 infusion. The secondary endpoints include the objective response rate (ORR), disease control rate (DCR), time to response (TTR), duration of response (DOR), progression-free survival (PFS), overall survival (OS) in efficacy evaluation, and changes in relevant pharmacokinetic (PK) indicators. The exploratory endpoint is the change in pharmacodynamic (PD) indicators. Clinical trial information: CTR20234065. Research Sponsor: Qingdao Sino-Cell Biomedicine Co., Ltd.