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CLINICAL UPDATE FROM A PHASE 1, FIRST-IN-HUMAN, OPEN-LABEL SINGLE AGENT STUDY OF SUPLEXA THERAPEUTIC CELLS IN PATIENTS WITH METASTATIC SOLID TUMOURS AND HAEMATOLOGIC MALIGNANCIES

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Background SUPLEXA is a first-in-class, autologous, adoptive immunotherapy; prepared from patients' PBMCs it contains NK cells, NKT-like, gd T cells, and ab T cells of both the CD8⁺ and CD4⁺ variety primed for broad tumor cytolytic activity.

Methods This is a FIH Phase 1, non-comparative, open-label, basket-design study NCT05237206. The study is enrolling up to 40 participants in Australia in 2 cohorts: 1. Solid tumours cohort that includes subjects with histologically or cytologically or radiographically confirmed and 2. a haematologic malignancies cohort including subjects with histologically or cytologically confirmed multiple myeloma, lymphoma, and chronic lymphocytic leukemia. Primary objective is to assess safety and tolerability of SUPLEXA and the secondary objective is to assess the efficacy. All eligible subjects will receive a minimum 7.5 x 10⁹ cumulative dose of SUPLEXA therapeutic cells. Each treatment is administered at least 1 week apart at Day 1 (baseline), Week 1, Week 2 and possibly more depending on manufacturing yield. The first 3 subjects in each cohort will be enrolled in a staggered manner, at least 1 week apart; these subjects will be evaluated for safety and if no safety concerns are identified, all remaining subjects will be enrolled. All subjects will be evaluated for DLTs, 1 week after the 1st dose and 2nd dose (prior to administration of 2nd dose and 3rd dose, respectively).

Results As of submission, 10 patients (8 female and 2 male; age 34-75years) have been enrolled. Cancer types have included squamous cell, ovarian, bladder, urothelial and pancreatic cancers. SUPLEXA therapy was successfully manufactured for all patients to receive the minimum course of 7.5 x 10⁹ SUPLEXA cells. Treatment has been well tolerated with no study related SAEs or discontinuations. No clinical observations have been noted with clinical chemistry, hematology, urinalysis, or other serology, nor with ECG or other assessments. Of note there has been a mild transient observation of odour for 24hrs post infusion as commonly expected from the DMSO cellular cryopreservative used. Data for the first 3 participants has been reviewed by the DSMB and the study is now fully opened to enrolment.

Conclusions Trial is proceeding well with an excellent tolerability profile and ease of administration for the patients. Additional safety and efficacy data will be forthcoming.

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Trial Registration NCT05237206

Ethics Approval Ethics approval received from Belberry HREC

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