TOPLINE SAFETY AND EFFICACY UPDATE OF SUPLEXA-101, A FIRST-IN-HUMAN, SINGLE AGENT STUDY OF SUPLEXA THERAPEUTIC CELLS IN 28 PATIENTS WITH METASTATIC SOLID TUMOURS

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Background SUPLEXA is a first-in-class, autologous, adoptive immunotherapy; prepared from patients' PBMCs that contains cytolytic populations of NK cells, NKT-like, gd T cells, and ab CD8/CD4 T cells.

Methods This is a FIH Phase 1, non-comparative, open-label, basket-design study NCT05237206. The study has enrolled 28 patients in Australia with histologically or cytologically or radiographically confirmed cancer for whom standard of care have failed. All have received the minimum dosing regimen of 2.5 billion cells per dose for at least 3 weekly treatments with continued SUPLEXA dosing depending on manufacturing yield. The primary objective was to determine safety and tolerability of SUPLEXA cell therapy and with the secondary objective was to assess efficacy.

Results To date, 28 patients have been enrolled. As an open label trial, cancer types have included renal cell, colorectal, TNBC, lung, melanoma, ovarian, liver and others. We demonstrate successful GMP SUPLEXA manufacturing for all enrolled patients to receive the minimum course of 3 cell treatments and > 90% exceeded this minimum.

SAFETY: Treatment was well tolerated with no study related serious adverse events (SAE) or discontinuations. The one TEAE related to therapy was a did report a mild unpleasant odour lasting for 3 days post infusion (expected from the DMSO in the cryopreservative). No negative or unusual clinical measurements of clinical chemistry, hematology, urinalysis, serology, or ECG or other assessments were detected.

EFFICACY: Of the 22 patients with clinical measurements to date, > 70% had attained stable disease (SD) and a response duration mean of 19 weeks ranging up to 35 weeks post SUPLEXA treatment. Two colorectal cancer patients have showed early partial response (PR).

Conclusions We present overall positive clinical findings for SUPLEXA-101 autologous cellular therapy for differing types of cancers in patients with end stage solid tumours and metastases. SUPLEXA cell therapy showed excellent safety and tolerability in all patients that were treated with multiple weekly doses. Greater than 70% of the patients showed early signals of SD or PR by RECIST criteria. This FIH trial is now closed to enrolment with plans the next SUPLEXA clinical trial underway now that safety and encouraging efficacy clinical outcomes have been established.

Trial Registration NCT05237206

Ethics Approval Approval was obtained from BellBerry 2021–10-1150

All participants signed PICF before starting the trial

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