TPS2682 Poster Session

Phase 1 clinical trial of autologous T-cells genetically engineered with a chimeric receptor to target the follicle-stimulating hormone receptor (FSHR) in recurrent ovarian cancer (OVCA).

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Background: FSHR is a tissue specific antigen expressed in $>$ 55% of high-grade epithelial OVCAs with negligible FSHR expression in non-ovarian tissues. OVCA xenografts treated with FSHCER T (FSH-Chimeric Endocrine Receptor + T-Cell (CER T)) cells demonstrated cytotoxic activity against patient-derived FSHR+ ovarian carcinomas. We hypothesize targeting FSHR in women with FSHR+ OVCA will result in improved response rates due to engraftment, expansion, and survival of these adoptively transferred FSHCER T-cells and will have acceptable toxicity. **Methods:** The primary objective of this phase 1 dose-escalation study (NCT05316129) in high-grade epithelial OVCA using T-cells genetically modified to express CER targeting FSHR is to assess the safety of the intraperitoneal (IP) and intravenous (IV) infusions of FSHCER T-cells. Secondary objectives include antitumor efficacy, persistence of transferred FSHR T cells, expansion of endogenous tumor-targeted cells, and comparison of IP and IV administration routes. Patients unable to be treated in the IP arm may be treated in the IV arm in the lowest unfilled cohort for that arm. Cohorts of 3 to 6 patients will be infused with escalating doses of FSHCER T-cells to establish the maximum tolerated dose (MTD) with 6 planned dose levels from 1 x10^5 to 1 x 10^7 cells/kg with the 5^{th} level receiving lymphodepleting chemotherapy. Following MTD determination, an expansion phase will be initiated. Nine patients have been enrolled in the first three dose-level cohorts. Eight have cleared the DLT period and one patient is currently being treated. One patient received a second dose of 3 x 10^5 cells/kg after 20 months apparent stable disease. Cohorts 1 and 2 correlates are being processed. NCT05316129. Moffitt Scientific Review #21113. Advarra Institutional Review Board #00000971. Clinical trial information: 05316129. Research Sponsor: Anixa BioSciences Inc., San Jose CA, USA.