AACR 2020

Promising evidence from innovative cell therapies emerging beyond heme malignancies

TILs demonstrate encouraging activity in advanced NSCLC patients who did not derive optimal benefit from Nivolumab[1]

- Adoptive cell therapy using TILs was given to NSCLC patients (after lymphodepletion) who progressed on or had SD when treated with Nivolumab (N=13 of 20 patients in Phase I study).
- Despite progression on Nivo, TIL therapy led to tumor shrinkage, with a best ORR of 25% – 2 ongoing CRs, 1 PR, 2 unconfirmed PRs, and 1 unconfirmed PR that is ongoing and awaiting a patient's next CT scan.
- BORR was expected to increase to 33% if ongoing unconfirmed PR is confirmed that will support further evaluation.

Successful generation of a novel cNET (clonal neo-antigen reactive T cells) methodology demonstrates feasibility in the first-in-human studies[2]

- Clonal neo-antigens are likely to be present on all tumor cells but not normal tissues, and given that TILs are not genetically modified, clonal neo-antigen-reactive T cells are anticipated to be better tolerated than engineered T-cell products.
- Achilles' proprietary technology for prediction of clonal antigens, the VELOSTM process incorporating the PELEUSTM bio-informatic approach, was successfully demonstrated to be a novel effective approach for the generation of autologous T-cell products (ATL001).
- ATL001 was composed of a mixed population of CD4+ and CD8+ T cells, both of which have been shown to be important for the maintenance of long-term cytotoxic responses.
- Potential to be directed to exquisitely target specific sets of clonal neo-antigens in NSCLC and melanoma patients.

Next gen CAR-T cell therapies show early signs of CR in R/R ALL[3,4]

Bi-specific CD19/CD22 CAR-T cells in R/R B-ALL

- Results from a Phase I study (NCT03448393) evaluating the bi-specific CD19/CD22 CAR-T cells in patients with relapsed/refractory B-cell precursor ALL, demonstrated clinical activity with reversible cytokine release syndrome (CRS) and limited neurotoxicity (13 patients were treated).
- 5 of 12 evaluable patients had CRs, and were MRD negative (4 were CAR-naïve); 33% patients had PR, with 3 patients in remission at a median of 7 months post-infusion.
- Despite all responders displaying CAR-T cell expansion, persistence was limited, reflected by the median peak % of CAR-T cells in the peripheral blood being 7% (range, 0-55). So far, 2 of 5 patients have relapsed with CD19/CD22-positive disease.
- A longer follow-up and a larger cohort study are likely warranted.

TruUCAR™ GC027 in R/R T-ALL

- Preliminary data from the clinical investigator initiated trial (IIT) evaluating the safety and efficacy of TruUCAR™ GC027, the first-in-human, universal CAR-T therapy for R/R T-ALL (with CD7+ expression, N=5) showed very promising early RR with no neurotoxicity events or acute GvHD.
- Five patients received a single infusion, of which all achieved a complete remission (4 had MRD negative CR) with or without complete blood count recovery (CR/CRi).

References:
2020 AACR Virtual Annual Meeting I; April 27-28, 2020.
1. **Creelan B, Wang C, Teer J, et al. Abstract CT056**
2. **Samuel E, et al. Abstract CT054**
3. **Shalabi H, Yates B, Shahani S, et al. Abstract CT051**
4. **Wang X, et al. Abstract CT052**

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