Initial results from dose escalation of a phase 1/2, first-in-human, open label study of AU-007, a monoclonal antibody that binds to IL-2 and prevents its binding to CD25, in patients with solid tumors.

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Presented at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), November 8-12, 2022

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**Study Design**

- **AU-007 Background**
  - Redirects IL-2 to T-effector / NK Cells and Away From Tregs and Vascular Endothelium
    - AU-007 is a computationally designed (Biolojic Design), human IgG1 recombinant antibody.
    - AU-007 binds trimeric IL-2 with high affinity and completely blocks its binding to CD25, without blocking the binding to CD122.
  - AU-007 uniquely tips the balance toward immune activation, away from immune suppression.
    - AU-007 is a human IgG1 monoclonal antibody.
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- **AU-007 Dose Escalation Phase 1/2a**
  - Initial results from dose escalation of a phase 1/2, first-in-human, open label study of AU-007, a monoclonal antibody that binds to IL-2 and prevents its binding to CD25, in patients with solid tumors.
  - As of the October 28 data cutoff, 4 patients have been enrolled into dose escalation, Arm 1A, AU-007 monotherapy.
  - All 4 patients had NSCLC, 3 had squamous histology, 1 had adenocarcinoma.
  - Pt 1 – NSCLC (squamous) 0.5 mg/kg biweekly for 5 doses.
  - Pt 2 – NSCLC (squamous) 1.5 mg/kg biweekly for 5 doses.
  - Pt 3 – Pancreatic 0.5 mg/kg biweekly for 5 doses.
  - Pt 4 – Pancreatic 1.5 mg/kg biweekly for 5 doses.

- **Duration of Treatment and Efficacy Details**
  - Duration of treatment: 0.5 mg/kg for 5 doses, 1.5 mg/kg for 5 doses.
  - Efficacy: 2 of the 3 evaluable patients have a best response of stable disease with some tumor shrinkage seen in one patient, and continue on study treatment.
  - Pharmacokinetics: No other IL-2 therapeutic with comparable clinical data is in phase 1/2 clinical trials.

- **Pharmacodynamics**
  - Unique MOA Addresses the IL-2 Negative Feedback Loop
    - Tumor cytokine activating effector cells against tumors are suppressed by an autocrine-inducible IL-2-dependent negative feedback loop.
    - This IL-2 negative feedback loop limits the effectiveness of IL-2 treatments and is a major barrier to achieving tumor responses.

- **Results**
  - AU-007 binds to IL-2 and prevents its binding to CD25 without blocking the binding to CD122.
  - AU-007 is the first IL-2 therapeutic to be evaluated in clinical trials.
  - AU-007 is being evaluated in a 140 patient dose escalation study in combination with a single loading dose of aldesleukin, or IL-2, with both AU-007 and aldesleukin given every 2 weeks.
  - AU-007 is the first IL-2 therapeutic to be evaluated in a clinical trial.
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- **Pharmacokinetics**
  - All 4 patients had NSCLC, 3 had squamous histology, 1 had adenocarcinoma.
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- **Safety**
  - No other IL-2 therapeutic with comparable clinical data is in phase 1/2 clinical trials.

- **Conclusions**
  - All 4 patients had NSCLC, 3 had squamous histology, 1 had adenocarcinoma.
  - The decrease in Tregs results in an increase in the CD8/Treg ratio.
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**Abstract ID: 775**

Received: 10/28/2022

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