PEGylated human IL-10 (AM0010) in advanced solid tumors

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**Background and Purpose**
- IL-10 is a natural cytokine that is crucial for the regulation of various immune responses.
- The study aimed to evaluate the efficacy and safety of AM0010, a PEGylated human IL-10 (PEG-rHuIL-10), in patients with advanced solid tumors.

**Mechanism of Action**
- IL-10 activates CD8+ T cells and PEGylated IL-10 (AM0010) induces the long-term "anti-tumor immune memory".

**Study Design**
- Parts A and B: Monotherapy and Combination therapy with Chemo- or Imuno-therapy.

**Results**
- **AM0010 Monotherapy Dose Escalation**
  - Patient self-administered daily doses of 10-100 µg/kg AM0010.
  - 12 patients, 4 patients had disease control (50%).
  - 2 patients had a tumor reduction of -92% after 28 weeks of treatment.

- **AM0010 Monotherapy Dose Escalation**
  - Biomarkers of efficacy observed: AM0010 increases activated CD8+ T cells in the blood but not in the tumor, and increased CD8+ T cells in the serum.

- **AM0010 Monotherapy RCC Best Response**
  - 6 (25%) of 24 evaluable patients had a partial response (PR). 2 (8%) had stable disease.
  - 1 patient had a tumor reduction of -92% after 28 weeks of treatment with delayed response.

**Conclusion and Outlook**
- Preclinical research and the conceptual convergence of the mechanism of action support synergies between AM0010 and immune checkpoint inhibitors.

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**References**
- Fridman, Pages et al. NRI 2012; Oft. CIR 2014 (Reviews)

**Support**
- ARMOR Biologics being developed by ARMO Biopharma.