The benefit of adding nal-irinotecan or oxaliplatin to 5-FU in second-line therapy for PDAC is still being debated. In a recent study, the combination of AM0010 with 5-FU and oxaliplatin (FOLFOX) showed promising results.

**Background and Purpose**

Background: Mechanism of Action

- Phosphorylation of the STAT1 and STAT3
- Treatment with 5-FU + oxaliplatin (FOLFOX) increased the IL-10 receptor on CD8+ T cells, which induced cytotoxicity, proliferation, and expansion of antigen-specific intratumoral CD8+ T cells.
- The increase in CD8+ T cells was not observed with FOLFOX alone, suggesting a synergistic anti-tumor effect of AM0010 with FOLFOX.

**Study Design and Eligibility**

- AM0010 + FOLFOX in Pancreatic Cancer Patients
  - Key Eligibility in AM0010 + FOLFOX PDAC Dose Expansion Cohort
    - All patients with resected PDAC are allowed
    - No prior platinum-containing regimen
    - No prior irinotecan or oxaliplatin
    - No prior chemotherapy or targeted therapy
- AM0010 Monotherapy in PDAC - OS
  - Monotherapy with AM0010 was administered at 20 µg/kg or 40 µg/kg, with a dose escalation to 100 µg/kg or 150 µg/kg.
- AM0010 in Pancreatic Cancer Patients
  - Monotherapy with AM0010 was administered at 20 µg/kg or 40 µg/kg, with a dose escalation to 100 µg/kg or 150 µg/kg.

**Results**

- AM0010 + FOLFOX in Pancreatic Cancer Patients
  - **Tumor Cell Infiltration**
    - The number of CD8+ T cells in the tumor center prior to treatment but not MHCI expression correlates with OS.
    - More than 5 fold expanded unique T cell clones in the blood appear to correlate with objective tumor response.
  - **Cell Death**
    - Early signs of apoptosis were observed with AM0010 + FOLFOX, suggesting a pro-apoptotic effect.
  - **Apoptosis**
    - AM0010 treatment induced a comprehensive immune activation signature (83 tested).

**Summary and Outlook**

- AM0010 + FOLFOX has an acceptable tolerability profile.
- AM0010 is being developed by ARMO BioSciences.
- For more information, visit clinicaltrials.gov (NCT02009449) or contact CONTACT INFORMATION.

**Information**

**REFERENCES**

Research supported by ARMO BioSciences. For more information, visit clinicaltrials.gov (NCT02009449) or contact CONTACT INFORMATION.