# Abstract #344999: A phase II open-label study of CPI-613 in combination with modified (m) FOLFIRINOX in patients with locally advanced pancreatic cancer

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## Background/Rationale:

- Locally advanced pancreatic adenocarcinoma (LAPC) accounts for ~35% of all pancreatic cancer (PC) diagnoses. Neoadjuvant strategies are needed to improve resectability and overall survival.
- CPI-613 (devimistat) targets mitochondrial pyruvate dehydrogenase and α-ketoglutarate dehydrogenase (fig 1).
- Phase I for metastatic PC showed addition CPI-613 to mFOLFIRINOX was safe and suggested impressive response (Alistar et al. Lancet Oncol 2017)

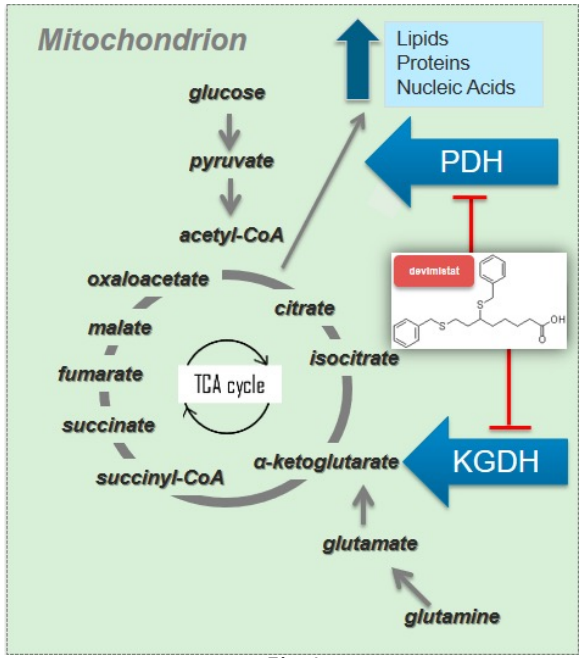


Fig 1.

Phase II enrollment ***complete, 37 pts enrolled***.

Now enrolling: dose-***escalation*** cohort.

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## Study Design:

- Tumor Assessments every 4 cycles (~8 weeks)
- Treatment as below D 1-3 of 14 day cycle

| | Day 1 | Day 2 | Day 3 |
|---|---|---|---|
| CPI-613 | 500 mg/m2 | | 500 mg/m2 |
| 5-Fluorouracil (as bolus) | 400 mg/m2 | | |
| Leucovorin | 400 mg/m2 | | |
| Irinotecan | 140 mg/m2 | | |
| Oxaliplatin | 65 mg/m2 | | |
| 5-Fluorouracil (Infusion) | 2400 mg/m2 | | |

- Primary endpoint mOS
- Secondary endpoints resection rate and PFS
- Correlative examination of immune subsets and metabolomics ongoing.

## Study Updates:

- Phase II enrollment complete October, 2020
- 27 (72%) Unresectable/ 10 (18%) Borderline at study entry
- Enrollment will continue with dose escalation cohorts studying 750 mg/m2 and 1000 mg/m2 in this population.