**PHASE II STUDY OF THERAPY SELECTED BY TUMOR MOLECULAR PROFILING IN PATIENTS WITH PREVIOUSLY TREATED METASTATIC PANCREATIC CANCER. A STUDY OF THE SU2C CONSORTIUM**


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**Abstract**

**Background:** A significant number of patients with chemotherapy-resistant pancreatic cancer (PC) have an advanced performance status (PS) and are not candidates for conventional chemotherapy. This phase II trial was designed to evaluate the feasibility of a personalized therapy approach in this patient population.

**Methods:** Tumor tissue was obtained from 50 patients at 10 centers. Histologic and clinical data were collected, and 49 subjects were accrued between August 2010-January 2012. NCI-60 cell line expression and the Panc-Xeno bank at Johns Hopkins University were used to assess drug sensitivity. Genomic and pathway analysis was conducted by CGH and IHC. Treatment recommendations were based on multiple methods.

**Results:** Forty Nine subjects were accrued between August 2010-January 2012. There were no major complications due to biopsy. Fourteen patients were excluded: 7 had deteriorating status, 6 had insufficient tissue on biopsy, 1 had unacceptable organ function, 1 had metastatic disease outside the pancreas. Forty-three subjects received therapy. The most common regimens/agents recommended were FOLFIRI, FOLFOX, irinotecan and doxorubicin.

**Conclusions:** This is the first "personalized therapy" study for pancreatic cancer. Feasibility and roadmap for future demonstrations is demonstrated. Patients with PS 1 or 2 and adequate bone marrow, kidney and liver function may be candidates for this regimen. Preliminary results indicate clinical benefit seen with FOLFIRI, irinotecan, FOLFOX and nab-paclitaxel/5FU.

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**Treatment Algorithm:** based on Von Hoff et al. JCO 28: 4879-83, 2010

<table>
<thead>
<tr>
<th>Priority</th>
<th>Methodology</th>
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<tbody>
<tr>
<td>1</td>
<td>Same target identified by IHC, Clinical Pathway Bank</td>
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<tr>
<td>2</td>
<td>Same target identified by IHC, CGH</td>
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<tr>
<td>3</td>
<td>Same target identified by IHC and CGH</td>
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<tr>
<td>4</td>
<td>Target identified by IHC</td>
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**Summary and Future Plans**

- This is the first "personalized therapy" study for pancreatic cancer. Feasibility and roadmap for future demonstrations is demonstrated.
- High expression 3 targets identified in most cases on IHC and many more on Microarray
- Deregulated DNA repair pathway: BRCA1, Topo2, and ERCC1, are targets for monoclonal antibody or inhibitor immunotherapy.