Phase 1 Trial in Pancreatic Adenocarcinoma (TACTOPS)

JUNE 1, 2020
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Pancreatic Cancer Overview

Pancreatic cancer is the seventh leading cause of global cancer deaths and the third leading cause of cancer death in the U.S.

Prevalence

- In 2017, there were an estimated 78,969 people living with pancreatic cancer in the U.S.
- Estimated new cases in 2020: 57,600
- Estimated deaths in 2020: 47,050

Survival Rates

- Local (pancreas): Accounts for 10% of cases; 5-year survival rate is 37%
- Regional (lymph nodes): 29% of cases; 5-year survival rate is 12%
- Distant (Stage IV or metastatic): More than half of all cases (53%) are diagnosed at the distant stage; 5-year survival rate is 3%
- Overall 5-year survival rate = 10%

Combination Treatment

- SOC for front-line unresectable pancreatic cancer: Chemotherapy (FOLFIRINOX or Gemcitabine/nab-paclitaxel)
- Less than 20% of patients are candidates for surgery (resectable) because cancer has usually spread by the time of diagnosis

Sources: National Cancer Institute, National Institutes of Health, American Cancer Society, Pancreatic Cancer Action Network
We commissioned an outside statistician to analyze the expected PFS for patients consistent with the eligibility of BCM Ph1 TACTOPS study by removing patients who progressed during the first 3 months of chemotherapy alone.

FOLFIRINOX (ACCORD study)

FOLFIRINOX

Hazard ratio, 0.47 (95% CI, 0.37–0.59)
P < 0.001.

mPFS = 6.4 months

Modified mPFS = 8 months

Nab-Paclitaxel-Gemcitabine (MPACT study)

Nab-Paclitaxel-Gemcitabine

mPFS = 5.5 months

Expected PFS based on Baylor Ph1 Eligibility

Modified mPFS = 6.8 months
MultiTAA-Specific T Cell Therapy in First-Line Setting

Demonstrates benefit on top of standard-of-care chemotherapy in patients with advanced and metastatic pancreatic cancer

ASCO 2020 Presentation

“A phase I trial targeting advanced or metastatic pancreatic cancer using a combination of standard chemotherapy and adoptively transferred nonengineered, multiantigen specific T cells in the first-line setting (TACTOPS)”

Observations

✓ MultiTAA-specific T cells was well tolerated when administered to patients with advanced pancreatic cancer, along with SOC chemotherapy

✓ In some patients, addition of T cells extended duration of first-line therapy, controlled cancer and induced additional tumor responses

✓ Clinical benefit correlated with detection of tumor-reactive T cells in patient peripheral blood

✓ T cells exhibited activity against targeted antigens and non-targeted TAAs, indicating induction of antigen/epitope spreading

✓ No infusion-related systemic- or neuro-toxicity
Brandon G. Smaglo, M.D., FACP

Associate Professor, Department of Gastrointestinal (GI) Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

TACTOPS study conducted by Baylor College of Medicine
A Phase I Trial Targeting Advanced or Metastatic Pancreatic Cancer using a Combination of Standard Chemotherapy and Adoptively Transferred Nonengineered, Multiantigen Specific T Cells in the First-Line Setting (TACTOPS)

Brandon G Smaglo, MD, FACP
ACCORD-11: FOLFIRINOX

• First line option for metastatic disease
• Toxic
  • Not all patients can tolerate
  • Cannot continue indefinitely
• mOS 11.1 months
• mPFS 6.4 months

MPACT: gemcitabine/nabpaclitaxel

- First line option for metastatic disease
- Thought of as less toxic
- mOS 8.5 months
- mPFS 5.5 months

Pancreatic Cancer: Treatment

• Combination chemotherapy (FFX or G/A)  
  – Non-chemotherapy options very limited

• Side effects  
  – Cumulative: fatigue, neuropathy, cytopenias  
  – Repetitive: nausea, vomiting, diarrhea  
  – Distressing: alopecia, cold-hypersensitivity

• T cell therapy options attractive for exploration
Patient

Blood draw

PBMCs

Antigen Specificity

Adoptive T cell transfer

Tumor-specific T cells

Infusion
T cell therapy for pancreatic cancer
Challenge: Tumor heterogeneity
Immune Escape
Our approach

• Simultaneously target multiple TAAs

• Target multiple epitopes (CD4 and CD8) within each antigen

• T cells with native T cell receptor specificity (non-engineered)
MultiTAA T cell therapy for PDAC

MAGEA4
PRAME
Survivin
NYESO1
SSX2

MultiTAA T cells
# TAA Expression in PDAC

<table>
<thead>
<tr>
<th>TAA</th>
<th>Expression in PDAC</th>
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<tbody>
<tr>
<td>Survivin</td>
<td>&gt;75%&lt;sup&gt;1-2&lt;/sup&gt;</td>
</tr>
<tr>
<td>SSX family</td>
<td>3-30%&lt;sup&gt;3-5&lt;/sup&gt;</td>
</tr>
<tr>
<td>MAGE-A family</td>
<td>20-86%&lt;sup&gt;3, 5-8&lt;/sup&gt;</td>
</tr>
<tr>
<td>PRAME</td>
<td>&gt;30%&lt;sup&gt;9&lt;/sup&gt;</td>
</tr>
<tr>
<td>NY-ESO-1</td>
<td>2-10%&lt;sup&gt;3, 5&lt;/sup&gt;</td>
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</tbody>
</table>

MultiTAA-T Cell Generation

Overlapping pepmixes

DC

PBMCs

Activation

Expansion

MultiTAA T cells
Profile of MultiTAA-T cells

Phenotype

% expression

Safety

% specific lysis

E:T 20:1

n=54
MultiTAA T cell specificity

Specificity

SFC/2x10^5

Targeted antigens

control

Survivin
NY-ESO-1
MAGE-A4
SSX2
PRAME
no pepmix

n=54
Clinical Trial: TACTOPS

• 6 Infusions, fixed cell dose (1x10⁷/m²) - no lymphodepletion

• Receive 3 months chemotherapy
  • Procurement performed and T cells generated

• If cancer controlled after 3 months, start receiving monthly T cell infusions along with ongoing chemotherapy
Clinical Trial: TACTOPS

• Primary endpoints – safety, feasibility
• Exploratory – efficacy

• 13 patients infused
  • Sufficient cells generated for all 6 infusions for 12 patients
  • 2 doses generated for the remaining patient
Radiographic CR : pt#7

Prior to multiTAA T cells

6 months post multiTAA T cells

Targeted antigens

Non-targeted antigens

Baseline  Peak post

Baseline  Peak post
Clinical response: pt#1

Prior to multiTAA T cells

2 months post multiTAA T cells

>30% reduction of index lesion

Targeted antigens

Non-targeted antigens

SFC/2x10^5

Baseline

Peak post

Survivin
NYESO1
MAGEA4
SSX2
Prame

WT1
AFP
MART1
MC1
MA3
MA2
MA1

Before: 40.4mm

2 months post: 27.4mm
Clinical response: pt#3

Prior to multiTAA T cells:
- 6 months post multiTAA T cells:
  - >40% reduction of index lesion

Targeted antigens:
- Survivin
- NYESO1
- MAGEA4
- SSX2
- Prame

Non-targeted antigens:
- WT1
- AFP
- MART1
- MC1
- MA3
- MA2B
- MA1

SFC/2x10^5

Baseline
Peak post

>40% reduction of index lesion
Clinical response: pt#12

Prior to multiTAA T cells

6 months post multiTAA T cells

Targeted antigens

Non-targeted antigens

SFC/2x10^5

Baseline  Peak Post

Targeted antigens:
- Survivin
- NYESO1
- MAGEA4
- SSX2
- Prame

Non-targeted antigens:
- WT1
- AFP
- MART1
- MC1
- MA3
- MA2B
- MA1

SFC/2x10^5

Baseline  Peak Post
Aggregate Tumor Measurements

Tumor Size (cm)

- Patient 1
- Patient 2
- Patient 3
- Patient 4
- Patient 5
- Patient 6
- Patient 7
- Patient 8
- Patient 9
- Patient 10
- Patient 11
- Patient 12
- Patient 13

Start T cells

1 Year Therapy

- Baseline
- 3 mths ChemoTx
- Post #3 infusion
- Post #6 infusion
- 3 mths Post T cells
- 6 mths Post T cells
Radiographic CR: pt#7

Tumor Size (cm)

Baseline 3 mths ChemoTx

Start T- cells
Radiographic CR : pt#7

- Tumor Size (cm)
- Start T cells
  - 1 Year Therapy
  - 3 mths ChemoTx
  - Post #3 infusion
  - Post #6 infusion

Baseline
3 mths
Post #3 infusion
Post #6 infusion
Enhanced Responses

Tumor Size (cm)

- Patient 1
- Patient 3
- Patient 12

- Start T cells
- 1 Year Therapy

- Baseline
- 3 mths ChemoTx
- Post #3 infusion
- Post #6 infusion
- 3 mths Post T cells
- 6 mths Post T cells
Arresting Progression

Tumor Size (cm)

- Patient 8
- Patient 10

Baseline 3 mths ChemoTx Post #3 infusion Post #6 infusion 3 mths Post T cells 6 mths Post T cells

Start T cells 1 Year Therapy
MultiTAA T cells + Chemo Summary

gemcitabine + nabpaclitaxel

Modified mPFS  Historical mOS

Pt 1
Pt 5
Pt 6
Pt 8

Months

Patient  Best RECIST response on T cell therapy
1  Partial Response
5  Progressive Disease
6  Stable Disease
8  Stable Disease

Died  Remained on study  Progressed

Chemotx  Chemotx + T cells  On-going chemotx
MultiTAA T cells + Chemo Summary

FOLFIRINOX

- **Modified mPFS**
- **Historical mOS**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Best RECIST response on T cell therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Mixed response</td>
</tr>
<tr>
<td>3</td>
<td>Partial Response</td>
</tr>
<tr>
<td>4</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>7</td>
<td>Radiographic Complete Response</td>
</tr>
<tr>
<td>9</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>10</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>11</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>12</td>
<td>Partial Response</td>
</tr>
<tr>
<td>13</td>
<td>Progressive Disease</td>
</tr>
</tbody>
</table>

Legend:
- Chemotx
- Chemotx + T cells
- On-going chemotx
- Died
- Remain on study
- Progressed
CA 19-9 trends

- **CA 19-9 (U/mL)**
- **Months**

### Participants
- **pt 1**
- **pt 2**
- **pt 3**
- **pt 4**
- **pt 5**
- **pt 6**
- **pt 7**
- **pt 8**
- **pt 9**
- **pt 10**
- **pt 11**
- **pt 12**
- **pt 13**

**Legend:**
- **Blue**
- **Gray**
- **Green**

**Key Events:**
- **START T-CELLS**

**Graphs:**
- The graphs show trends of CA 19-9 levels over time for different participants, with arrows indicating the timing of T-cell therapy.

**Note:** The data points for each participant are plotted over the months, with CA 19-9 levels on the y-axis and months on the x-axis. The arrows signify the start of T-cell therapy, suggesting a correlation between therapy and changes in CA 19-9 levels.
Treatment Summary

- No additional side effect when adding t-cell therapy
- Durable cancer control with 9/13 patients exceeding historical control of overall survival
- Measurable tumor responses in 4 patients
Conclusions

• Feasible to manufacture multiTAA T cells
• Well tolerated
• Encouraging cancer treatment results
• In vivo expansion of tumor-specific T cells observed
• Antigen spreading
Future

• Encouraging effects seen with chemotherapy
• Explore first line therapy in advanced cancer with earlier t-cell initiation
• Refine which antigens to target
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