Advanced Antibody-Based Therapeutics

- Oncology
- Autoimmune Diseases

Jefferies 2016 Global Healthcare Conference
Peter P. Pfreundschuh, VP Finance and CFO
Forward-Looking Statements

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Highlights

• Multiple programs focused on cancers with unmet need

• Validated first-in-class antibody-drug conjugate (ADC) platform technology for solid cancer therapy
  – Lead ADC (IMMU-132) granted Breakthrough Therapy Designation (BTD) from FDA in metastatic triple-negative breast cancer (TNBC)

• Several additional novel agents to continue pipeline progress

• Key near-term events (6 - 12 months) for IMMU-132
  – Commercial-scale production from outside CMOs
  – Phase 3 pivotal trial in TNBC planned in calendar year 2016
  – BTD opens pathway for accelerated approval
  – Valuable asset for partnering
Broad Pipeline of Antibody-Based Therapies

**Sacituzumab govitecan/IMMU-132** (anti-Trop-2-SN-38 antibody-drug conjugate)

- **Metastatic triple-negative breast cancer**
  - FDA granted BTD
- **Metastatic solid cancers (lung/urothelial/esophageal)**

**Labetuzumab govitecan/IMMU-130** (anti-CEACAM5-SN-38 antibody-drug conjugate)

- **Metastatic colorectal cancer**

**Epratuzumab** (humanized anti-CD22)

- **Pediatric acute lymphoblastic leukemia** *

*The International clinical trial on childhood relapsed acute lymphoblastic leukemia (IntReALL) is funded by the European Commission.

**Other product candidates**

- Veltuzumab (anti-CD20) for cancer and autoimmune diseases
- Milatuzumab (anti-CD74) for autoimmune diseases
- IMMU-114 (anti-HLA-DR) for hematologic malignancies
Potential characteristics of difficult-to-treat tumors
- Not responsive to prior therapies
- Protected by surrounding layer of connective tissue
- Often become metastatic

Components of IMMU’s antibody-drug conjugation platform (ADC)
- Highly specific MAb that is targeted to cancer cells
- Specially designed “payload” drug that delivers a concentrated dose to the tumor
- A linker designed to release the payload at the tumor site

Immunomedics’ Next Generation ADC Technology Platform
1. Reduced toxicity
2. Greater dose of drug to tumor
3. Opportunity for long-term, repeated treatments
What Makes IMMU’s ADCs Different?

- Unique approach to ADC therapeutics for cancer
  - Highly cancer-specific antibodies based on 30 years of experience
  - Utilize moderately potent payloads: increased therapeutic index

- Proprietary linker for rapid payload release at or inside tumor
  - High drug-to-antibody ratio (~7.6:1)

- SN-38 payload
  - Active metabolite with more potency than its parent compound, irinotecan (a commonly used chemotherapy)
  - ADCs’ unique chemistry avoids low solubility and selectively delivers SN-38 to the tumor

- Two ADCs completed Phase 2: IMMU-132 and IMMU-130
IMMU-132 Targets a Variety of Solid Tumors

• Mechanism of action
  – Binds Trop-2, which is highly expressed on many epithelial cancer cells
  – IMMU-132 is internalized into the tumor cells before SN-38 is released

• Breakthrough Therapy designation from FDA in metastatic triple-negative breast cancer

• U.S. Fast Track designation in triple-negative breast, non-small-cell and small-cell lung cancers

• U.S. Orphan Drug status in small-cell lung and pancreatic cancers

• Encouraging results from Phase 1/2 reported
  – Mild and manageable toxicity at recommended doses
  – Numerous objective responses or long-term disease stabilization in heavily pretreated patients; including patients previously treated with topoisomerase or checkpoint inhibitors
  – Multiple treatment cycles administered
# IMMU-132: Summary Efficacy
(Patients with at least one post-treatment response evaluation)

Meaningful responses in patients having multiple prior therapies
Phase 1 / 2 clinical trials

<table>
<thead>
<tr>
<th>Cancer Type(^1)</th>
<th>Number of Patients</th>
<th>% ORR(^2)</th>
<th>Median PFS (months)(^3)</th>
<th>% PFS Maturity</th>
<th>Median OS (months)</th>
<th>% OS Maturity</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNBC</td>
<td>60</td>
<td>33%</td>
<td>5.6</td>
<td>81%</td>
<td>14.3</td>
<td>40%</td>
</tr>
<tr>
<td>NSCLC</td>
<td>46</td>
<td>26%</td>
<td>3.9</td>
<td>48%</td>
<td>10.5</td>
<td>31%</td>
</tr>
<tr>
<td>SCLC</td>
<td>33</td>
<td>24%</td>
<td>3.6</td>
<td>83%</td>
<td>8.1</td>
<td>50%</td>
</tr>
<tr>
<td>UC</td>
<td>14</td>
<td>50%</td>
<td>6.9</td>
<td>47%</td>
<td>11.4(^4)</td>
<td>16%</td>
</tr>
</tbody>
</table>

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2. Objective response rate (%ORR) = (complete response + partial response)/number of patients.
3. Based on number of intent-to-treat patients of 61, 45, 36 and 14 for TNBC, NSCLC, SCLC and UC, respectively.
4. Mean OS result reported.

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TNBC results as of May 2016, NSCLC and SCLC results presented at 2016 ASCO, UC results presented at PEGS Boston 2016.
IMMU-132: Best Response from TNBC Patients
60 assessable (10 mg/kg)

Objective response (CR + PR) = 33%  Confirmed response (RECIST 1.1) = 28%
Median # prior chemotherapies = 5 (range, 2 – 12)

2 patients not shown received 1 dose and withdrew from study
• 1 patient was found to have brain metastases
• The other patient died of her disease

62 patients with 2 or more prior lines of therapy that included a taxane enrolled
2 excluded because <3 doses given.

Data on file as of May 2016
IMMU-132: Best Response from NSCLC Patients
46 assessable (8 and 10 mg/kg)

Objective response (CR + PR) = 26%        Confirmed response (RECIST 1.1) = 13%

Median # prior therapies = 3 (range, 1 – 7)

54 patients enrolled; 6 have not had their first assessment; 2 excluded because <3 doses given.

6 PD patients not shown
- 4 patients failed to have 1st CT re-assessment
- 2 patients with new lesion without a target lesion assessment

* squamous cell  8 = 8 mg/kg  c, confirmed PR
- 1st assessment, confirmed pending

Partial response
Stable disease
Progression
Progression; new lesion or non-target lesion

Presented at 2016 ASCO.
IMMU-132: Best Response from SCLC Patients
33 assessable (8 and 10 mg/kg)

Objective response (CR + PR) = 24%
Confirmed response (RECIST 1.1) = 9%

Median # prior therapies = 2 (range, 1 – 5)

36 patients enrolled; 2 excluded because <3 doses given; 1 withdrew with unrelated AE prior to response assessment.
IMMU-132: Best Response from UC Patients
14 assessable (8 and 10 mg/kg)

Objective response (CR + PR) = 50%
Confirmed response (RECIST 1.1) = 50%

Median # prior therapies = 2 (range, 1 – 5)

23 patients enrolled; 6 have not had their first assessment; 3 excluded because <3 doses given.
**IMMU-132: Mild, Predictable and Manageable Toxicity**

Starting Dose of 10 mg/kg (N=128 Patients)

<table>
<thead>
<tr>
<th>Interim Adverse Events (ranked by Grades 3+)</th>
<th>Grade 3+</th>
<th>All Grades</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>34%</td>
<td>59%</td>
</tr>
<tr>
<td>Anemia</td>
<td>15%</td>
<td>39%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>11%</td>
<td>54%</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>11%</td>
<td>19%</td>
</tr>
<tr>
<td>Febrile neutropenia</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>8%</td>
<td>41%</td>
</tr>
</tbody>
</table>

- Camptosar (irinotecan) US Prescribing Information (USPI) “boxed warnings”
  - Early and late forms of diarrhea can occur (Grades 3 & 4: 38%)
  - Severe myelosuppression may occur (Neutropenia: Grades 3 & 4: 31%)
- No pretreatment of patients prior to receiving IMMU-132 required by protocol
- No anti-antibody responses detected to-date, even after repeated dosing
IMMU-130 in Metastatic Colorectal Cancer

• **Mechanism of action**
  – Binds to CEACAM5 on colorectal and other tumor cells
  – SN-38 is released locally from IMMU-130 for diffusion into tumor cells

• **Promising activity in metastatic CRC previously treated with irinotecan therapy**

• **Acceptable safety profile in heavily pretreated patients**
  (n=75, all doses, occurrence >2%, Grade 3 and 4)
  – Neutropenia (15%)
  – Diarrhea (7%)
  – Febrile neutropenia (3%)

• **Repeated doses given over months without interfering host antibodies**
## IMMU-130: Efficacy in Metastatic Colorectal Cancer

<table>
<thead>
<tr>
<th></th>
<th>Once Weekly Dosing</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>8 mg/kg</td>
</tr>
<tr>
<td><strong>Number of Patients</strong></td>
<td>21</td>
</tr>
<tr>
<td><strong>Median Progression-Free Survival (PFS) (months)</strong></td>
<td>4.8 (3.9 – 6.2)</td>
</tr>
<tr>
<td><strong>Maturity PFS</strong></td>
<td>90%</td>
</tr>
<tr>
<td><strong>Median Overall Survival (OS) (months)</strong></td>
<td>7.5 (5.7 – 16.1)</td>
</tr>
<tr>
<td><strong>Maturity OS</strong></td>
<td>67%</td>
</tr>
</tbody>
</table>

Median PFS of 3.9 months and median OS of 6.7 months in 20 patients with prior treatment with regorafenib, bevacizumab, 5-fluorouracil, irinotecan and oxaliplatin-containing chemotherapies.
Financial Highlights (As of March 31, 2016)

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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<tbody>
<tr>
<td>Basic shares outstanding</td>
<td>95 million</td>
</tr>
<tr>
<td>Market capitalization</td>
<td>$237 million</td>
</tr>
<tr>
<td>Debt (convertible senior notes)</td>
<td>$100 million</td>
</tr>
<tr>
<td>Cash, cash equivalents and marketable securities</td>
<td>$62 million</td>
</tr>
<tr>
<td>Forecast FY 2016 annual cash burn (6/30/16)</td>
<td>$52-54 million</td>
</tr>
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</table>
# Meaningful Anticipated Upcoming Events

<table>
<thead>
<tr>
<th>Program</th>
<th>Event</th>
<th>Expected Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMU-132</td>
<td>Initiate Phase 3 pivotal trial in metastatic triple-negative breast cancer</td>
<td>2H 2016</td>
</tr>
<tr>
<td>IMMU-132</td>
<td>Continue Phase 2 patient enrollment in breast, lung, urothelial, and brain cancers</td>
<td>2016</td>
</tr>
<tr>
<td>IMMU-130</td>
<td>Complete Phase 3 trial design in metastatic colorectal cancer</td>
<td>2016</td>
</tr>
</tbody>
</table>