Phase Ia/Ib Dose-Escalation Study of the Anti-TIGIT Antibody Tiragolumab as a Single Agent and in Combination with Atezolizumab in Patients with Advanced Solid Tumors

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1 Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN, 2 Princess Margaret Hospital, Toronto, Ontario, Canada, 3 Seoul National University, Seoul, Korea, 4 Yale University, New Haven, CT, 5 Dana-Farber Cancer Institute, Boston, MA, 6 HonorHealth Research Institute, Scottsdale, AZ, 7 Memorial Sloan Kettering Cancer Center, New York, NY, 8 Peter MacCallum Cancer Center, Melbourne, Australia, 9 Hospital Univ Vall d'Hebron; Barcelona, Spain, 10 Institut Bergonie, Bordeaux, France, 11 Samsung Medical Center, Seoul, Korea, 12 Hospital Clinico Universitario de Valencia, Valencia, Spain, 13 University of California Los Angeles, Los Angeles, CA, 14 START Madrid-CIOCC, Madrid, Spain, 15 ICO L'Hospitalet; Barcelona, Spain, 16 Hospital del Mar, Barcelona, Spain, 17 Institut Gustave Roussy, Villejuif, France, 18 Centre Léon Bérard, Lyon, France, 19 Institut Claudius Regaud; Toulouse, France, 20 Kinghorn Cancer Centre; Darlinghurst, Australia, 21 Clinica Universitaria de Navarra; Navarra, Spain, 22 Johns Hopkins , Baltimore, MD, 23 Institut Curie, Paris, France, 24 Genentech, Inc. South San Francisco, CA, 25 F. Hoffmann-La Roche, Basel, Switzerland, 26 Severance Hospital, Yonsei, Seoul, Korea, 27 Asan Medical Center, Seoul, Korea
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• I will discuss investigational use of the anti-TIGIT antibody tiragolumab (MTIG7192A) in my presentation.
TIGIT Inhibits the Immune Response

- TIGIT (T cell immunoreceptor with Ig and ITIM domains) is a novel inhibitory receptor expressed on multiple immune cells (T cells and NK cells)\(^1\)-\(^4\)

1. TIGIT inhibits T and NK cells by binding to PVR

2. TIGIT down-modulates APCs

3. TIGIT binds to and blocks CD226 (activating)

**Diagram:**
- TIGIT inhibits T and NK cells by binding to PVR
- TIGIT down-modulates APCs by binding to PVR and blocking CD226
- TIGIT binds to and blocks CD226 (activating)

**Text:**
- APC = antigen-presenting cell; NK = natural killer; PVR = poliovirus receptor; Teff = T effector; Treg = T regulatory
- Adapted from Manieri et al. Trends Immunology 2017

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\(^1\) Yu et al. *Nature Immunology* 2009; \(^2\) Johnston et al. *Cancer Cell* 2014; \(^3\) Manieri et al. *Trends Immunology* 2017; \(^4\) Rotte et al. *Annals of Oncology* 2018
**TIGIT is Co-Expressed with PD-1**

**Background:**
TIGIT expression correlates with PD-1, especially in tumor-infiltrating T cells, and is often co-expressed on the same cell.

**Hypothesis:**
Anti-TIGIT antibodies, which prevent TIGIT from binding, may restore anti-tumor response and enhance anti-PD-L1 antibodies.

APC = antigen-presenting cell; NK = natural killer
In preclinical mouse models, combination treatment with anti-TIGIT and anti-PD-L1 antibodies synergistically improves tumor control and prolongs survival.

Figure adapted from Johnston et al. Cancer Cell 2014
Tiragolumab is an Anti-TIGIT Antibody

- Tiragolumab is a fully human IgG1/kappa anti-TIGIT monoclonal antibody with an intact Fc region that blocks the binding of TIGIT to its ligand PVR and to the co-activating receptor CD226

- Study GO30103 is a first in-human Phase I study of tiragolumab as a single agent (Phase Ia) and in combination with the anti-PD-L1 antibody atezolizumab (Phase Ib) in patients with advanced solid tumors (NCT02794571)
  - Stage I: Dose-escalation
  - Stage II: Dose-expansion at the recommended Phase II dose (RP2D)
Study Objectives

Primary Objectives

• *Phase Ia*: To determine the preliminary safety, tolerability, and RP2D of tiragolumab

• *Phase Ib*: To determine the preliminary safety, tolerability, and RP2D of tiragolumab in combination with atezolizumab

Secondary Objectives

• To determine the pharmacokinetics of tiragolumab as a single agent and in combination with atezolizumab

• To determine the preliminary anti-tumor activity of tiragolumab as a single agent and in combination with atezolizumab
Study Design: Phase Ia Dose-Escalation

**Phase Ia: Tiragolumab**

**Dose-Escalation**

- Tiragolumab administered as fixed-dose IV every 3 weeks (Q3W)
- Dose-liming toxicity (DLT) window of 21 days
- Backfill enrollment permitted in cleared dose levels

<table>
<thead>
<tr>
<th>Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200</td>
</tr>
<tr>
<td>600</td>
</tr>
<tr>
<td>400</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>30</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

Data cutoff: 2 Dec 2019
Study Design: Phase Ia with Concurrent Phase Ib

**Phase Ia: Tiragolumab**

<table>
<thead>
<tr>
<th>Dose-Escalation</th>
<th>1200 mg</th>
<th>600 mg</th>
<th>400 mg</th>
<th>100 mg</th>
<th>30 mg</th>
<th>8 mg</th>
<th>2 mg</th>
</tr>
</thead>
</table>

**Phase Ib: Tiragolumab + Atezolizumab**

<table>
<thead>
<tr>
<th>Dose-Escalation</th>
<th>1200 mg + Atezo</th>
<th>600 mg + Atezo</th>
<th>400 mg + Atezo</th>
<th>100 mg + Atezo</th>
<th>30 mg + Atezo</th>
<th>8 mg + Atezo</th>
<th>2 mg + Atezo</th>
</tr>
</thead>
</table>

- Concurrent dose-escalation in Phase Ib with increasing dose of tiragolumab Q3W with atezolizumab at fixed dose of 1200 mg IV Q3W
- Backfill enrollment permitted in cleared dose levels in Phase Ia and Phase Ib
- Patients with disease progression in Phase Ia could crossover to Phase Ib

Results of dose-escalation in Phase Ia and in Phase Ib will be presented today

Data cutoff: 2 Dec 2019
Study Design: Concurrent Expansion Cohorts

**Phase Ia: Tiragolumab**

- **Dose-Expansion**
  - 1200 mg
  - 600 mg
  - 400 mg
  - 100 mg
  - 30 mg
  - 8 mg
  - 2 mg

- **Dose-Escalation**
  - 1200 mg
  - 600 mg
  - 400 mg
  - 100 mg
  - 30 mg
  - 8 mg
  - 2 mg

**Phase Ib: Tiragolumab + Atezolizumab**

- **Dose-Escalation**
  - 1200 mg + Atezo
  - 600 mg + Atezo
  - 400 mg + Atezo
  - 100 mg + Atezo
  - 30 mg + Atezo
  - 8 mg + Atezo
  - 2 mg + Atezo

- **Dose-Expansion**
  - 600 mg + Atezo
  - 400 mg + Atezo
  - Non-Small Cell Lung Cancer
  - Other Solid Tumors

**Results of Phase Ib NSCLC Expansion Cohort will be presented today**

*Data cutoff: 2 Dec 2019*

- Expansion cohorts in tumor types with tiragolumab doses ≥ 400 mg Q3W in Phase Ia and in Phase Ib with atezolizumab
Key Eligibility Criteria

**Key Inclusion Criteria**
- Patients with advanced solid tumors for whom standard therapy does not exist or is ineffective
- Age ≥ 18 years
- ECOG performance of 0 or 1
- Measurable disease per RECIST v1.1
- *Expansion cohorts only*: PD-L1-positive tumors not previously treated with cancer immunotherapy (CIT-naïve)
  - PD-L1 measured with the Ventana SP142 immunohistochemistry assay

**Key Exclusion Criteria**
- Prior anti-TIGIT therapy
- Anti-cancer therapy within 3 weeks or palliative radiation within 2 weeks
- Discontinuation of prior cancer immunotherapy due to immune-mediated Grade ≥ 3 adverse events
- Prior active or untreated central nervous system metastases
- History of autoimmune disease
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Phase Ia: Tiragolumab (n=24)</th>
<th>Phase Ib: Tiragolumab + Atezo (n=49)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years, median (range)</strong></td>
<td>59.5 (40-77)</td>
<td>54.0 (25-81)</td>
</tr>
<tr>
<td>Male</td>
<td>10 (42%)</td>
<td>24 (49%)</td>
</tr>
<tr>
<td>ECOG PS 1</td>
<td>17 (71%)</td>
<td>36 (74%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15 (63%)</td>
<td>30 (61%)</td>
</tr>
<tr>
<td>Asian</td>
<td>7 (29%)</td>
<td>13 (27%)</td>
</tr>
<tr>
<td><strong>Prior cancer therapies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2 (8%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>2</td>
<td>6 (25%)</td>
<td>14 (29%)</td>
</tr>
<tr>
<td>3</td>
<td>6 (25%)</td>
<td>10 (20%)</td>
</tr>
<tr>
<td>≥4</td>
<td>10 (42%)</td>
<td>18 (37%)</td>
</tr>
</tbody>
</table>

ECOG = Eastern Cooperative Oncology Group; PS = performance status
# Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic, n (%)</th>
<th>Phase Ia: Tiragolumab (n=24)</th>
<th>Phase Ib: Tiragolumab + Atezo (n=49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary cancer history type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>4 (17%)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>Rectum</td>
<td>4 (17%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Breast</td>
<td>2 (8%)</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>Non-small cell lung cancer</td>
<td>-</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Head and neck cancer</td>
<td>-</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Ovarian</td>
<td>1 (4%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Other*</td>
<td>13 (54%)</td>
<td>15 (31%)</td>
</tr>
</tbody>
</table>

* Other includes:

- **Phase Ia**: endometrial (n=2), melanoma (n=2); and appendiceal, bladder, cervical, cholangiocarcinoma, kidney, neuroendocrine, peritoneum, sarcoma, and stomach (n=1 each)

- **Phase Ib**: sarcoma (n=4), stomach (n=2), melanoma (n=2); and anus, appendiceal, bladder, esophagus, GE junction, Merkel cell, and peritoneum (n=1 each)

Data cutoff: 2 Dec 2019
### Patient Disposition

- Dose escalation completed for each dose level in Phase Ia and Phase Ib

<table>
<thead>
<tr>
<th>Status, n (%)</th>
<th>Phase Ia: Tiragolumab (n=24)</th>
<th>Phase Ib: Tiragolumab + Atezo (n=49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>On treatment</td>
<td>0 (0%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Discontinued</td>
<td>24 (100%)</td>
<td>44 (90%)</td>
</tr>
<tr>
<td>Progression of disease</td>
<td>10 (42%)</td>
<td>37 (76%)</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>2 (8%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Crossover to Phase Ib</td>
<td>12 (50%)</td>
<td>--</td>
</tr>
</tbody>
</table>

Data cutoff: 2 Dec 2019
Safety Summary of Adverse Events

- No DLTs were observed across all dose levels in Phase Ia and Phase Ib

<table>
<thead>
<tr>
<th></th>
<th>Phase Ia: Tiragolumab (n=24)</th>
<th>Phase Ib: Tiragolumab + Atezo (n=49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any-cause adverse event</td>
<td>24 (100%)</td>
<td>46 (94%)</td>
</tr>
<tr>
<td>Grade 3-5 adverse event</td>
<td>6 (25%)</td>
<td>28 (57%)</td>
</tr>
<tr>
<td>Related Grade 3-5 adverse events*</td>
<td>1 (4%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>6 (25%)</td>
<td>26 (53%)</td>
</tr>
<tr>
<td>AE leading to study drug(s) interruption</td>
<td>4 (17%)</td>
<td>12 (25%)</td>
</tr>
<tr>
<td>AE leading to study drug(s) withdrawal**</td>
<td>0</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

* Related AEs in Phase Ia was Grade 3 blood creatinine increased (n=1). No Grade 5 AEs were associated with tiragolumab. Related AEs in Phase Ib were Grade 3 hyperlipasemia (n=1) and Grade 3 lymphocyte count decreased (n=1). No Grade 5 AEs were associated with tiragolumab and/or atezolizumab.

** One patient withdrew from the Phase Ib study for gastrointestinal complaints related to clinical progression.

Data cutoff: 2 Dec 2019
All Adverse Events ≥ 10% in Phase Ia

Data cutoff: 2 Dec 2019

All-Cause Adverse Events

- Fatigue
- Vomiting
- Constipation
- Decreased Appetite
- Abdominal Pain
- Musculoskeletal Pain
- Nausea
- Pain in Extremity
- Pruritis
- Arthralgia
- Cough
- Hypomagnesemia
- Insomnia
- Malignant Progression*
- Myalgia
- Urinary Tract Infection

Adverse Events Related to Tiragolumab

- Fatigue
- Vomiting
- Constipation
- Decreased Appetite
- Abdominal Pain
- Musculoskeletal Pain
- Nausea
- Pain in Extremity
- Pruritis
- Arthralgia
- Cough
- Hypomagnesemia
- Insomnia
- Malignant Progression*
- Myalgia
- Urinary Tract Infection

Relative Frequency (%)

* Grade 5 AEs were malignant neoplasm progression (n=3), not related to tiragolumab.
All Adverse Events ≥ 10% in Phase Ib

Data cutoff: 2 Dec 2019

Grade 5 AEs were malignant neoplasm progression (n=12) and pulmonary embolism (n=2), not related to study drug(s).
### All Immune-Mediated Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Phase Ia: Tiragolumab (n=24)</th>
<th>Phase Ib: Tiragolumab + Atezo (n=49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All immune-mediated AE</td>
<td>4 (17%)</td>
<td>29 (59%)</td>
</tr>
<tr>
<td>Grade 3-5 immune-mediated AE*</td>
<td>0</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Infusion-related reaction</td>
<td>2 (8%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Rash</td>
<td>2 (8%)</td>
<td>14 (29%)</td>
</tr>
<tr>
<td>Hepatitis (diagnosis and lab)</td>
<td>1 (4%)</td>
<td>10 (20%)</td>
</tr>
<tr>
<td>Pancreatitis (lab)</td>
<td>1 (4%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td>0</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>0</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Anemia</td>
<td>0</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

* No Grade 5 immune-mediated AEs were associated with tiragolumab and/or atezolizumab.

Data cutoff: 2 Dec 2019
Pharmacokinetics of Tiragolumab

• The exposure of tiragolumab increased with dose, and the pharmacokinetics of tiragolumab are not altered in combination with atezolizumab.
Pharmacodynamics of Tiragolumab

• Complete and sustained occupancy of peripheral TIGIT receptors on CD8+ T cells and on NK cells was observed at tiragolumab doses ≥ 30 mg Q3W in Phase Ia

![Graph showing % TIGIT receptors available for binding to tiragolumab at different doses for CD8+ T cells and NK cells over study days.](image)

Data cutoff: 2 Dec 2019
Phase Ia Dose-Escalation: Tiragolumab

Data cutoff: 2 Dec 2019

Best % Change in SLD

Bladder > Gastric > Colon > Endometrial > Sarcoma > Colon > Bile Duct > Rectal > Endometrial > Breast > Rectal > Melanoma > Rectal > Appendix > Cervical > Mucosal Mel > Colon > TNBC > Neuroendocrine > Ovarian > Rectal > Ovarian

PD-L1
SP142

TC/IC 0 or 1
TC/IC 2 or 3

Data cutoff: 2 Dec 2019
Phase Ib Dose-Escalation: Tiragolumab + Atezo

Data cutoff: 2 Dec 2019

Best % Change in SLD

Melanoma
Gastric
NSCLC
Esophageal
Rectal
Sarcoma
Ovarian
Anal
HNSCC
TNBC
Colon
TC/IC 0 or 1
PD-L1
SP142

Prior Cancer
Immunotherapy (CIT)

TC/IC 2 or 3

TC/IC 0 or 1

Data cutoff: 2 Dec 2019
Recommended Phase II Dose for Tiragolumab

- Tiragolumab at 600 mg Q3W was chosen as the recommended Phase II dose:
  - Complete and sustained peripheral receptor occupancy occurred at tiragolumab doses ≥ 30 mg
  - Clinical activity for tiragolumab occurred at 400 mg to 600 mg, as determined by partial responses in the Phase Ib

- Expansion cohorts were then initiated with tiragolumab and atezolizumab in PD-L1-positive cancer immunotherapy (CIT)-naïve indications, including metastatic NSCLC
Phase Ib: CIT-Naïve PD-L1 Positive NSCLC Expansion

ORR = 46% (6/13)
DCR = 85% (11/13)

Data cutoff: 2 Dec 2019
Phase Ib: CIT-Naïve PD-L1-Positive NSCLC Expansion

Best Response
- CR
- PR
- SD
- PD
- Ongoing

Days on Study

% Change in SLD

Data cutoff: 2 Dec 2019
Conclusions

• Tiragolumab was well-tolerated in Phase Ia and with atezolizumab in Phase Ib
  - No dose-limiting toxicities occurred across all dose levels in Phase Ia or Phase Ib
  - The safety profile of tiragolumab appears similar to other checkpoint inhibitors

• The exposure of tiragolumab increased with dose, and the pharmacokinetics of
  tiragolumab are not altered in combination with atezolizumab
  - Complete and sustained occupancy of peripheral TIGIT receptors was observed at
    tiragolumab doses ≥ 30 mg Q3W
  - Recommended Phase II dose of tiragolumab is 600 mg Q3W in combination with
    atezolizumab 1200 mg Q3W
Conclusions

• No objective responses occurred in Phase Ia, although most patients had tumor types not typically responsive to CIT, were PD-L1-negative, or were heavily pre-treated

• Objective responses occurred in Phase Ib, mainly in CIT-naïve PD-L1 positive tumors
  - In a PD-L1 positive NSCLC expansion cohort (n=13), confirmed ORR was 46%, with several responses showing durability

• Based on the preliminary safety and activity in this study, the combination of tiragolumab + atezolizumab is being tested in a randomized, placebo-controlled Phase II study in NSCLC (CITYSCAPE, NCT03563716)

  [Rodriguez-Abreu et al., ASCO 2020]
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