Activating the patient’s immune system to fight cancer

Oncolytic Virotherapy Summit
Boston - 5 December 2018
Important
NOTICE AND DISCLAIMER

This report contains certain forward-looking statements based on uncertainty, since they relate to events and depend on circumstances that will occur in future and which, by their nature, will have an impact on the results of operations and the financial condition of Targovax. Such forward-looking statements reflect the current views of Targovax and are based on the information currently available to the company. Targovax cannot give any assurance as to the correctness of such statements.

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Introduction

2. Pre-clinical data
3. Phase I single agent data
4. CPI refractory melanoma PD-1 combo data
5. Mesothelioma chemotherapy combo data
6. Summary
TARGOVAX AIMS TO ACTIVATE THE PATIENT’S IMMUNE SYSTEM TO FIGHT CANCER

- **Targovax focus**
- **Immune activators**
  - Oncolytic viruses, vaccines
- **Immune modulators**
  - Checkpoint inhibitors
- **Immune boosters**
  - CAR-Ts, TCRs
- **Targeted therapy**
  - TKIs, PARPs, etc.
- **Surgery - Radio - Chemo**
Targovax has two programs in clinical development, with an **ONCOLYTIC VIRUS LEAD PRODUCT CANDIDATE**

**ONCOS**

**Oncolytic virus**

**Lead product candidate**
- Genetically **armed adenovirus**
- Turns cold **tumors hot**
- Induces **tumor specific T-cells**
- Single agent **phase I completed**
- **4 ongoing combination trials**

**Pipeline product**
- **Shared neoantigen**, therapeutic peptide vaccine
- Triggers the **T-cell response** to oncogenic **RAS driver mutations**
- 32 patient **phase I/II trial completed**

Activates the immune system

Triggers patient-specific responses

No need for individualization
ONCOS-102 is an oncolytic adenovirus serotype 5 armed with a GM-CSF transgene.

1. Selective replication in cancer cells
2. Boosting the immune activation
3. Enhanced infection of cancer cells
BENEFITS OF ADENOVIRUS SEROTYPE 5 BACKBONE

Highly immunogenic, Toll like receptor 9 (TLR9) agonist

Well-characterized, well-tolerated and few safety concerns

Double stranded DNA, possibility for transgenes, non-enveloped

Pre-existing immunity, reduced issue of immuno-dominance
PRE-EXISTING IMMUNITY STRENGTHENS the *in situ* vaccination anti-tumor immune response

“…pre-existing immunity to NDV may increase its therapeutic efficacy through potentiation of systemic anti-tumor immunity, which provides clinical rationale for repeated therapeutic dosing and prompts investigation of such effects with other OV"s”

*Dmitry Zamarin et al. 2018*
2 Pre-clinical data

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**ONCOS-102 SYNERGY WITH CHEMOTHERAPY**

In mesothelioma mouse model

*In vivo* anticancer effect of ONCOS-102 and chemotherapy

% change in tumor volume

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**Effects observed at Day 60:**

- ONCOS-102 vs. mock
  - 56% tumor volume reduction
- ONCOS-102 vs. pem/cis
  - 63% tumor volume reduction
- ONCOS-102+pem/cis vs. pem/cis
  - 75% tumor volume reduction
- Combination synergy: ONCOS-102+pem/cis vs. ONCOS-102
  - 33% tumor volume reduction

Kuryk et al., Int J Cancer, 10 June 2016
ONCOS-102 SYNERGY WITH PD-1 BLOCKADE in melanoma mouse model

In vivo anticancer effect of ONCOS-102 & Keytruda®
% change in tumor volume

<table>
<thead>
<tr>
<th>Tumor volume reduction vs. vehicle control</th>
<th>% change by Day 40:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keytruda® only</td>
<td>No change</td>
</tr>
<tr>
<td>ONCOS-102 only</td>
<td>52% reduction p&lt;0.05</td>
</tr>
<tr>
<td>ONCOS-102 + Keytruda®</td>
<td>69% reduction p&lt;0.05</td>
</tr>
<tr>
<td>Combination synergy effect</td>
<td>35% reduction p&lt;0.05</td>
</tr>
</tbody>
</table>

1 A2058 cell line xenograft melanoma tumor model, non-responsive to Keytruda® monotherapy treatment
ONCOS-102 IMMUNE ACTIVATES TUMORS *IN VIVO* in melanoma mouse model\(^1\)

**CD8+ T-cell tumor infiltration** (TILs)
% of total CD3+ cell population

<table>
<thead>
<tr>
<th></th>
<th>Vehicle</th>
<th>ONCOS-102</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of CD3+ cells</td>
<td>18</td>
<td>45</td>
</tr>
</tbody>
</table>

**PD-L1 positive tumor cells**
% of tumor cells

<table>
<thead>
<tr>
<th></th>
<th>Vehicle</th>
<th>ONCOS-102</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of cells expressing PD-L1</td>
<td>8</td>
<td>16</td>
</tr>
</tbody>
</table>

\(^1\) A2058 cell line xenograft melanoma tumor model, non-responsive to Keytruda® monotherapy treatment

Kuryk et al. Oncoimmunity 2018
MESOTHELIN-SPECIFIC T-CELL RESPONSE
induced by ONCOS-102 in mesothelioma mouse model

*In vivo* antigen specific T-cell response
IFN-γ ELISPOT analysis for tumor antigen activated T-cells

Kuryk et al., 2018, J Med Virol;1–5
3 Phase I single agent data

4. CPI refractory melanoma PD-1 combo data
5. Mesothelioma chemotherapy combo data
6. Summary
ONCOS-102 CLINICAL DEVELOPMENT PROGRAM

Compassionate use program
115 patients

Phase I trial
12 patients
7 indications

CPI refractory melanoma
Phase I
up to 12+12 patients
- Combination with Keytruda
- CPI refractory PoC
- First 6 patients completed

Mesothelioma
Phase I/II - randomized
30 patients
- Combination with SoC chemo
- Path-to-market
- Orphan drug status

Peritoneal cancer
Phase I/II
up to 78 patients
- Combination with Imfinzi®
- Intraperitoneal administration
- Collaboration with MedImmune / AZ, CRI, & Ludwig

Prostate cancer
Phase I
up to 15 patients
- Combination with dendritic cell vaccine (DCVAC)
- Collaboration with Sotio

Completed
Ongoing trials sponsored by Targovax
Ongoing trials sponsored by partner
ONCOS-102 PHASE I SINGLE AGENT DATA

Compassionate use program
115 patients

Phase I trial
12 patients
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ONCOS-102 Phase I trial design:
- 12 patients, 7 different solid tumors
- All refractory to multiple lines of therapy
- ONCOS-102 monotherapy
  - 9 injections over 5 months

Top-line results:
- 100% innate immune activation
- 11/12 patients increase in CD8+ T-cells
- 40% SD, 2 long-term survivors
- Abscopal effect and lasting systemic immune responses observed

Cold tumor turned hot, CD8+ T-cell staining

Pre-treatment Baseline

Post-treatment Week 8

Ranki et al., Journal for Immunotherapy of Cancer 2016, 4(17)
ONCOS-102
Phase I proof of concept

**CD8+ T-CELL INFILTRATION CORRELATES WITH SURVIVAL**

**Case example**
- **Ovarian cancer**, 38yr old woman
- Failed on 5 types of chemotherapy
- **>1,000-fold increase** in TILs
- Tumor specific T-cells detected up to 2 years after treatment
- **Stable disease for 3 years**, survived for 3.5 years

**Fold-change CD8+ T-cell count vs. survival**

\[ r = 0.75 \quad p = 0.005 \]

- CD8+ fold-change from baseline vs. overall survival (months)
- **Ranki et al., Journal for Immunotherapy of Cancer 2016, 4(17)**
CPI refractory melanoma PD-1 combo data

5. Mesothelioma chemotherapy combo data
6. Summary
ONCOS-102 MELANOMA EARLY DATA

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
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<td>Mesothelioma</td>
<td>Phase I/II - randomized 30 patients</td>
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<tr>
<td>Combination with MedImmune / AZ, CRI, &amp; Ludwig</td>
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<td>Path-to-market</td>
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<td>Orphan drug status</td>
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ONCOS-102 & Keytruda combination

MELANOMA PHASE I TRIAL STUDY DESIGN

First read out autumn 2018:
• Six patients

CPO: Cyclophosphamide
ONCOS-102 INDUCES INNATE IMMUNE ACTIVATION in CPI refractory advanced melanoma

ONCOS-102 induction of systemic innate immune response
Cytokine expression, concentration in serum

![Graph showing cytokine expression over time](image-url)
INCREASED T-CELL TUMOR INFILTRATION
including in un-treated lesion

Tumor infiltrating lymphocytes (TILs)
Fold change from baseline

CD4+ TILs

CD8+ TILs
INCREASED LEVEL OF CYTOTOXIC CD8+ TILs
in patients with strongest immune activation

Granzyme B expressing CD8+ T-Cells (TILs)
Fold change from baseline

CD8+ GranzB+ TILs
### TUMOR SPECIFIC T-CELLS IN TUMOR BIOPSIES

**Tumor antigen specific T-cell response**
IFN-γ ELISPOT analysis for tumor antigen activated T-cells

<table>
<thead>
<tr>
<th>Patient</th>
<th>Tumor Antigen</th>
<th>Baseline</th>
<th>Week 3</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient 5</strong>&lt;br&gt;Previous Yervoy® &amp; Keytruda</td>
<td>MAGE-A1</td>
<td>-</td>
<td>+</td>
<td>Increased infiltration of MAGE-A1 tumor specific T-cells&lt;br&gt;- MAGE-A1 T-cells also detected at baseline</td>
</tr>
<tr>
<td><strong>Patient 4</strong>&lt;br&gt;Previous Yervoy, Keytruda &amp; Imlygic®</td>
<td>NY-ESO-1</td>
<td>-</td>
<td>+</td>
<td><em>De novo</em> induction of NY-ESO-1 tumor specific T-cells&lt;br&gt;- Not present at baseline</td>
</tr>
<tr>
<td>MAGE-A1</td>
<td>-</td>
<td>+</td>
<td><em>De novo</em> induction of MAGE-A1 tumor specific T-cells&lt;br&gt;- Not present at baseline</td>
<td></td>
</tr>
</tbody>
</table>
COMPLETE RESPONSE IN PATIENT 5
following ONCOS-102 and Keytruda combination treatment

**Patient 5**
Previous Yervoy & Keytruda

**Baseline**
Progression on Keytruda

**Week 3**
Visible tumor regression after 3x ONCOS-102 injections

**Week 9**
Complete response after 3x ONCOS-102 injections & 2x Keytruda infusions

**Patient 4**
Previous Yervoy, Keytruda & Imlygic

**Baseline**
No clinical benefit with Keytruda monotherapy

**Week 9**
SD – Transient tumor regression observed by clinical assessment

**By week 15**
Withdrawn due to distant metastasis
ONCOS-102 + KEYTRUDA MELANOMA TRIAL
one patient had a complete response by week 9

<table>
<thead>
<tr>
<th>1</th>
<th>Safety</th>
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<tbody>
<tr>
<td>✓ First safety review completed with no concerns</td>
<td></td>
</tr>
<tr>
<td>✓ ONCOS-102 and Keytruda combination is well-tolerated</td>
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</tbody>
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<table>
<thead>
<tr>
<th>2</th>
<th>Innate immune activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Systemic increase of pro-inflammatory cytokines (6/6 patients)</td>
<td></td>
</tr>
<tr>
<td>✓ All patients develop fever</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Adaptive immune activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Increase in tumor T-cell infiltration (TILs, 3/4 patients)</td>
<td></td>
</tr>
<tr>
<td>✓ Tumor-specific T cells in 2/4 patients</td>
<td></td>
</tr>
<tr>
<td>✓ Abscopal immune response in one patient</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Complete response in 1/6 patients (very rare)</td>
<td></td>
</tr>
<tr>
<td>✓ Transient regression in 3 patients</td>
<td></td>
</tr>
<tr>
<td>✓ Associated with level of immune activation</td>
<td></td>
</tr>
</tbody>
</table>
SECOND DOSE COHORT TO BE INITIATED
up to 12 additional patients who will receive 12 ONCOS-102 injections

From:
1st dose cohort
3x ONCOS-102 injections

To:
2nd dose cohort
12x ONCOS-102 injections

* = optional

CPO: Cyclophosphamide

CPO: Cyclophosphamide
5

Mesothelioma chemotherapy combo data

6. Summary
ONCOS-102 MESOTHELIOMA EARLY DATA

**Compassionate use program**
- 115 patients

**Phase I trial**
- 12 patients
- 7 indications

**CPI refractory melanoma**
- Phase I
- up to 12+12 patients
  - Combination with Keytruda
  - CPI refractory PoC
  - First 6 patients completed

**Mesothelioma**
- Phase I/II - randomized
- 30 patients
  - Combination with SoC chemo
  - Path-to-market
  - Orphan drug status

**Peritoneal cancer**
- Phase I/II
- up to 78 patients
  - Combination with Imfinzi
  - Intraperitoneal administration
  - Collaboration with MedImmune / AZ, CRI, & Ludwig

**Prostate cancer**
- Phase I
- up to 15 patients
  - Combination with dendritic cell vaccine (DCVAC)
  - Collaboration with Sotio

Completed
- Ongoing trials sponsored by Targovax
- Ongoing trials sponsored by partner
2 of 2 mesothelioma patients in Phase I trial showed that ONCOS-102 CAN TURN MESOTHELIOMA HOT

<table>
<thead>
<tr>
<th>CD8+ T-cells in tumor</th>
<th>CD4+ T-cells in tumor</th>
<th>PD-L1 positive tumor cells</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tumor biopsy staining</strong></td>
<td><strong>Fold change</strong></td>
<td><strong>% of total</strong></td>
</tr>
<tr>
<td><strong>Mesothelioma – Phase I, patient 14</strong></td>
<td>130x</td>
<td>6.5</td>
</tr>
<tr>
<td>Baseline</td>
<td>Week 5</td>
<td>Baseline</td>
</tr>
<tr>
<td><strong>Mesothelioma – Phase I, patient 9</strong></td>
<td>8.8x</td>
<td>2.1</td>
</tr>
<tr>
<td>Baseline</td>
<td>Week 5</td>
<td>Baseline</td>
</tr>
</tbody>
</table>

Ranki et al., Journal for Immunotherapy of Cancer 2016, 4(17)
ONCOS-102 in malignant pleural mesothelioma
PHASE I/II STUDY DESIGN IN COMBINATION WITH SoC

Patient population
Advanced malignant pleural mesothelioma
1st - 3rd line

Safety lead-in completed
ONCOS-102 plus SoC chemotherapy (6 cycles)

Experimental group (n=14)
ONCOS-102 plus SoC (6 cycles)

Control group (n=10)
SoC (6 cycles)

Non-randomized

Randomized part currently enrolling
Ongoing ONCOS-102 malignant pleural mesothelioma Phase I/II trial
SIGNAL OF EFFICACY IN THE FIRST 6 PATIENTS

1 Safety
✓ ONCOS-102 well-tolerated in combination with chemotherapy

2 Innate immune activation
✓ Systemic increase of pro-inflammatory cytokines in 6/6 patients

3 Adaptive immune activation
✓ Increase in tumor infiltration of CD4+ and CD8+ T-cells in 3/4 patients
✓ Tumor-specific T-cells in 2/6 patients

4 Efficacy
✓ One partial response (PR) and two stable disease (SD)
✓ 50% disease control rate
Summary
ONCOS CLINICAL DEVELOPMENT STRATEGY

1. Path-to-market
   - Orphan indication
     - Target launch indication
       - Mesothelioma
       - Orphan drug status
       - Combo with SoC chemo

2. Proof-of-concept
   - Reactivating CPI refractory cancers
     - Reactivating CPI refractory melanoma
     - Combo w/PD-1

3. Proof-of-concept
   - New CPI indication
     - Indications with no/limited effect of CPIs
       - Ovarian and colorectal cancer with spread to peritoneum
       - Combo w/PD-L1

4. Next generation oncolytic viruses
   - Platform expansion with new targets
     - Ongoing pre-clinical testing
     - Novel targets and mode-of-action
WHY ONCOS-102?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vivo efficacy</td>
<td>Innate immune activation</td>
<td>Adaptive immune activation</td>
<td>Efficacy</td>
</tr>
<tr>
<td><strong>Anti-tumor effect</strong></td>
<td><strong>Strong innate immune activation</strong> in nearly all injected patients</td>
<td><strong>Increase in T-cells</strong> systemically and in tumor (TILs)</td>
<td><strong>Complete response</strong> seen in CPI refractory melanoma patient</td>
</tr>
<tr>
<td><strong>Abscopal effect</strong></td>
<td><strong>Synergy with clinical outcome</strong></td>
<td><strong>Tumor-specific T-cells</strong> identified in several patients</td>
<td><strong>Outcome associated with immune activation</strong></td>
</tr>
<tr>
<td><strong>Tumor-specific immune responses</strong></td>
<td><strong>Correlation with clinical outcome</strong></td>
<td></td>
<td><strong>Well-tolerated</strong>, &gt;150 patients treated</td>
</tr>
</tbody>
</table>
# PIPELINE OVERVIEW AND MILESTONES

<table>
<thead>
<tr>
<th>Platform</th>
<th>Product candidate</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Last event</th>
<th>Next expected event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONCOS</strong> oncolytic adenovirus</td>
<td><strong>ONCOS-102</strong></td>
<td>Mesothelioma Comb. w/ pemetrexed/cisplatin&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>Phase Ib safety lead-in cohort, incl. immune activation and ORR data (6 pts)</td>
<td>1H 2020 Randomized ORR data 30 pts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Melanoma Comb. w/KEYTRUDA&lt;sup&gt;®&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>ORR and immune activation (6 pts), 1/6 CR</td>
<td>1H 2019 ORR and immune data first cohort</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peritoneal cancers&lt;sup&gt;2,3&lt;/sup&gt; Collab: Ludwig, CRI &amp; AZ Comb. w/IMFINZI&lt;sup&gt;®&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>First dose escalation cohort safety review (4 pts)</td>
<td>Update by collaborator, expected 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prostate&lt;sup&gt;3&lt;/sup&gt; Collab: Sotio Comb. w/DCVAC</td>
<td></td>
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<td></td>
<td>First patient dosed</td>
<td>Update by collaborator, expected 2019</td>
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<tr>
<td></td>
<td>Next-gen ONCOS</td>
<td>3 viruses undisclosed</td>
<td></td>
<td></td>
<td></td>
<td>Virus construct cloning and in vitro validation</td>
<td>2H 2019 Pre-clinical data</td>
</tr>
<tr>
<td><strong>TG</strong> neo-antigen cancer vaccine</td>
<td><strong>TG01</strong></td>
<td>Pancreatic cancer Comb. w/gemcitabine</td>
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<td></td>
<td>mOS 33.4 months Demonstrated mutant RAS-specific immune activation</td>
<td>TBD</td>
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<tr>
<td></td>
<td><strong>TG02</strong></td>
<td>Colorectal cancer Proof-of-mechanism Comb. w/KEYTRUDA&lt;sup&gt;®&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td>First safety review, incl. immune activation data (3 pts)</td>
<td>1H 2019 Immune activation and mechanistic data (mono)</td>
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<td></td>
<td><strong>TG02</strong></td>
<td>CPI synergy TG + PD-1</td>
<td></td>
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<td></td>
<td>2019 Pre-clinical data</td>
<td></td>
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</tbody>
</table>

<sup>1</sup> Current standard of care chemotherapy for patients with unresectable malignant pleural mesothelioma
<sup>2</sup> Patients with advanced peritoneal disease, who have failed prior standard chemotherapy and have histologically confirmed platinum-resistant or refractory epithelial ovarian or colorectal cancer
<sup>3</sup> Trials sponsored by collaborators

Ongoing collaborator sponsored trials
Ongoing ONCOS-102 malignant pleural mesothelioma Phase I/II trial

CLINICAL RESPONSES IN SAFETY COHORT

Safety lead-in cohort

- Partial response
- Stable disease
- Disease progression

1st line treatment

- 50% tumor reduction (CT)
- Partial metabolic response (PET)

2nd/3rd line treatment

- Stabilized tumor (CT)
- No metabolic change (PET)

- Previously progressed on pem/cis in 1st line
- Stabilized tumor (CT)
- Partial metabolic response (PET)
- 9x increase in CD8+ T cells in tumor
- 14x increase in CD4+ T cells in tumor
- De novo MAGE-A1 T-cells detected