Cervical Cancer and the Evolving Therapeutic Landscape

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Thursday, September 9, 2021
## Systemic Therapy for Cervical Cancer

**Squamous Cell Carcinoma, Adenocarcinoma, or Adenosquamous Carcinoma**

<table>
<thead>
<tr>
<th>Chemoradiation</th>
<th>Recurrent or Metastatic Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred Regimens</strong></td>
<td><strong>Preferred Regimens</strong></td>
</tr>
<tr>
<td>• Cisplatin</td>
<td>• Pembrolizumab + cisplatin/paclitaxel ± bevacizumab for PD-L1–positive tumors (category 1)¹,²,⁴,⁶,¹¹</td>
</tr>
<tr>
<td>• Carboplatin if patient is cisplatin intolerant</td>
<td>• Pembrolizumab + carboplatin/paclitaxel ± bevacizumab for PD-L1–positive tumors (category 1)¹,²,⁴,⁶,¹¹</td>
</tr>
<tr>
<td></td>
<td>• Cisplatin/paclitaxel/bevacizumab (category 1)¹,²</td>
</tr>
<tr>
<td></td>
<td>• Carboplatin/paclitaxel/bevacizumab (category 1)¹</td>
</tr>
</tbody>
</table>

**Other Recommended Regimens**

- Cisplatin/paclitaxel (category 1)³,⁴
- Carboplatin/paclitaxel (category 1 for patients who have received prior cisplatin therapy)
- Topotecan/paclitaxel/bevacizumab (category 1)¹,²
- Topotecan/paclitaxel²
- Cisplatin/topotecan⁷

### First-line Combination Therapy

<table>
<thead>
<tr>
<th>Recurrent or Metastatic Disease</th>
<th>Second-line or Subsequent Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred Regimens</strong></td>
<td><strong>Preferred Regimens</strong></td>
</tr>
<tr>
<td>• Pembrolizumab for PD-L1–positive or MSI-H/dMMR tumors⁶,⁷,¹¹</td>
<td>• Pembrolizumab for PD-L1–positive tumors (category 2A)¹³</td>
</tr>
<tr>
<td><strong>Other Recommended Regimens</strong></td>
<td><strong>Other Recommended Regimens</strong> (All agents listed here are category 2B unless otherwise noted)</td>
</tr>
<tr>
<td>• Carboplatin⁶</td>
<td>• Bevacizumab¹³</td>
</tr>
<tr>
<td>• Paclitaxel⁶,¹⁰</td>
<td>• Albumin-bound paclitaxel</td>
</tr>
<tr>
<td></td>
<td>• Docetaxel</td>
</tr>
<tr>
<td></td>
<td>• Fluorouracil</td>
</tr>
<tr>
<td></td>
<td>• Gemcitabine</td>
</tr>
<tr>
<td></td>
<td>• Ifosfamide</td>
</tr>
<tr>
<td></td>
<td>• Irinotecan</td>
</tr>
<tr>
<td></td>
<td>• Mitomycin</td>
</tr>
<tr>
<td></td>
<td>• Pemetrexed</td>
</tr>
<tr>
<td></td>
<td>• Topotecan</td>
</tr>
<tr>
<td></td>
<td>• Vinorelbine</td>
</tr>
</tbody>
</table>

Useful in Certain Circumstances

- Pembrolizumab for TMB-H tumors⁸,⁹
- Larotrectinib or entrectinib for NTRK gene fusion-positive tumors (category 2B)
KEYNOTE-826: Randomized, Double-Blind, Phase 3 Study

Key Eligibility Criteria
- Persistent, recurrent, or metastatic cervical cancer not amenable to curative treatment
- No prior systemic chemotherapy (prior radiotherapy and chemoradiotherapy permitted)
- ECOG PS 0 or 1

Stratification Factors
- Metastatic disease at diagnosis (yes vs no)
- PD-L1 CPS (<1 vs 1 to <10 vs ≥10)
- Planned bevacizumab use (yes vs no)

End Points
- Dual primary: OS and PFS per RECIST v1.1 by investigator
- Secondary: ORR, DOR, 12-mo PFS, and safety
- Exploratory: PROs assessed per EuroQol EQ-5D-5L VAS

Pembrolizumab 200 mg IV Q3W for up to 35 cycles +
Paclitaxel + Cisplatin or Carboplatin IV Q3W for up to 6 cycles³ +
Bevacizumab 15 mg/kg IV Q3W

Placebo IV Q3W for up to 35 cycles +
Paclitaxel + Cisplatin or Carboplatin IV Q3W for up to 6 cycles³ +
Bevacizumab 15 mg/kg IV Q3W

*Paclitaxel: 175 mg/m². Cisplatin: cisplatin 50 mg/m². Carboplatin: AUC 5 mg/mL/min. The 6-cycle limit was introduced with protocol amendment 2, although participants with ongoing clinical benefit who were tolerating chemotherapy could continue beyond 6 cycles after sponsor consultation.

CPS, combined positive score (number of PD-L1–staining cells [tumor cells, lymphocytes, macrophages] divided by the total number of viable tumor cells, multiplied by 100); PROs, patient-reported outcomes; VAS, visual analog scale. KEYNOTE-826 ClinicalTrials.gov Identifier, NCT03635567.
Keynote 826
PFS by PD-L1
1. CPS ≥ 1
2. ITT
3. CPS ≥ 10

Colombo et al NEJM 2021
Keynote 826
OS by PD-L1
1. CPS ≥ 1
2. ITT
3. CPS ≥ 10

Colombo et al NEJM 2021
Primary Stage IVB, persistent or recurrent carcinoma of the cervix
• Measurable disease by RECIST v1.1
• ECOG-PS: 0-1
• No previous systemic chemotherapy for advanced or recurrent disease
• Available tissue (archival or fresh)
• N=404 pts

Primary Endpoint:
Overall survival (OS)

Secondary Endpoints:
• PFS
• ORR
• DOR
• Safety
• HR-QOL

Control Arm
Cis- or carboplatin + paclitaxel + bevacizumab (GOG 240)
until disease progression, unacceptable toxicity, death or withdrawal of consent

Experimental Arm
Cis- or carboplatin + paclitaxel + bevacizumab + atezolizumab until disease progression, unacceptable toxicity, death or withdrawal of consent

Stratification Factors:
• Prior ChemoRT
• Histology: SCC vs Adeno (including AdenoSquamous)
• Chemotherapy Backbone: Cisplatin vs Carboplatin

ClinicalTrials.gov Identifier: NCT03556839
## Randomized Phase III ICI Trials in the Locally-advanced Setting

<table>
<thead>
<tr>
<th>Frontline ICI trial</th>
<th>Population</th>
<th>Agent (n)</th>
<th>Design</th>
<th>Primary endpoint(s)</th>
</tr>
</thead>
</table>
| CALLA (NCT03830866)            | • FIGO 2009 IB2-IIB node+  
• IIIA-IVA any nodal status  
• Measurable RECIST v1.1  
• ECOG PS: 0-1 | Durva (714) | 2 arm 1:1 CRT control 24 months            | • PFS               |
| ENGOT cx11/GOG 3047/KEYNOTE-A18 (NCT04221945) | • FIGO 2009 IB2-IIB node+  
• IIIA-IVA any nodal status  
• Measurable RECIST v1.1  
• ECOG PS: 0-1 | Pembro (980) | 2 arm 1:1 CRT control 24 months            | • PFS  
• OS               |

CRT, chemoradiotherapy; durva, durvalumab; ECOG PS, Eastern Cooperative Oncology Group performance status; FIGO, International Federation of Gynecology and Obstetrics; ICI, immune checkpoint inhibitor; OS, overall survival; pembro, pembrolizumab; RECIST, Response Evaluation Criteria in Solid Tumours
Tisotumab Vedotin (TV)

- Tisotumab vedotin is an investigational antibody–drug conjugate directed to TF and covalently linked to the microtubule-disrupting agent, MMAE, via a protease-cleavable linker\(^1,2\)
  - TF is a protein highly expressed in cervical cancer and other solid tumors\(^3-6\)
- Multimodal MOA of tisotumab vedotin\(^1,2,7\)
  - Direct cytotoxicity
  - Bystander killing
  - Immunogenic cell death
  - ADCC
  - ADCP

innovaTV 204 (NCT03438396) is a pivotal phase 2 single-arm, multicenter (United States and Europe) study evaluating tisotumab vedotin in patients with previously treated recurrent and/or metastatic cervical cancer

**Key Eligibility Criteria**
- Recurrent or extrapelvic metastatic cervical cancer
- Progressed during or after doublet chemotherapy with bevacizumab (if eligible)
- Received ≤2 prior systemic regimens
- ECOG PS 0-1

Enrolled: 102
Treated: 101

**Tisotumab vedotin**
2.0 mg/kg IV Q3W

Until PD or unacceptable toxicity

Tumor responses assessed using CT or MRI at baseline, every 6 weeks for the first 30 weeks, and every 12 weeks thereafter

*Study sample size calculated assuming a confirmed ORR of 21% to 25% with tisotumab vedotin and to provide ≥80% power to exclude an ORR of ≤11%

**Primary Endpoint**
- ORR per RECIST v1.1, by independent imaging review committee (IRC)

**Secondary Endpoints**
- ORR per RECIST v1.1, by investigator
- DOR, TTR, and PFS by IRC and investigator
- OS
- Safety

**Exploratory Endpoints**
- Biomarkers
- HRQoL

CT, computed tomography; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HR QoL, health-related quality of life; MRI, magnetic resonance imaging; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumours; TTR, time to relapse; Q3W, every 3 weeks

Maximum Change in Target Lesion Size by IRC Assessment

- Data cutoff: February 06, 2020. Median duration of follow-up: 10.0 months. + indicates a change greater than 100%. Horizontal dashed lines indicate 20% increase and 30% decrease in target lesion diameters from baseline for RECIST v1.1 assessment. Colored bars represent the best overall confirmed response. CR, PR, SD, and PD were based on RECIST v1.1 as evaluated by IRC.
- CR, complete response; IRC, independent review committee; PD, disease progression; PR, partial response; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; SD, stable disease.

- N=101
- Confirmed ORR (95% CI), % 24 (15.9–33.3)
- CR, n (%) 7 (7)
- PR, n (%) 17 (17)
- SD, n (%) 49 (49)
- PD, n (%) 24 (24)
- Not evaluable, n (%) 4 (4)

- Median DOR (95% CI) 8.3 months (4.2-NR)


PDUFA for accelerated US FDA approval 10/10/2021
Most Common TRAEs with TV


- Most TRAEs were grade 1 or 2 and no new safety signals were reported
- One death due to septic shock was considered by the investigator to be related to therapy

TRAEs with ≥10% incidence

- Alopecia: 64%
- Epistaxis: 38%
- Nausea: 30%
- Conjunctivitis: 27%
- Fatigue: 26%
- Dry eye: 24%
- Myalgia: 23%
- Anemia: 15%
- Arthralgia: 12%
- Decreased appetite: 11%
- Keratitis: 11%
- Itch: 10%

N=101

Grade 1 or 2
Grade ≥3

Ocular AEs were mostly mild to moderate, resolved, and were manageable with an eye care plan.

Most bleeding events were grade 1 epistaxis (28%) of which majority resolved.

Most peripheral neuropathy events (known MMAE-related toxicity) were grade 1 and manageable with dose modifications; resolution was limited by follow-up period.

Coleman RL. **Lancet Oncol.** 2021:S1470-2045(21)00056-5.
Genmab and Seagen Announce FDA Accelerated Approval for TIVDAK™ (tisotumab vedotin-tftv) in Previously Treated Recurrent or Metastatic Cervical Cancer

September 20, 2021 17:00 ET | Source: Genmab A/S

Prior bevacizumab administration (yes vs no)
Region (US: EU: Other)
Prior anti-PD-1 or PD-L1 administration (yes vs no)

* The proportion of participants who have not received prior bevacizumab in combination with chemotherapy as 1L treatment will be capped at 50%.
** Some AEIs may be followed longer than 30 days until resolution, improvement, or stabilization.
### innovaTV 205/ENGOT cx8/GOG 3024: TV Combinations and 1L

<table>
<thead>
<tr>
<th>2L+ escalation</th>
<th>Frontline expansion</th>
<th>2L+ expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>TV + bevacizumab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TV + pembrolizumab</td>
<td>TV + pembrolizumab</td>
<td>TV + pembrolizumab</td>
</tr>
<tr>
<td>TV + carboplatin</td>
<td>TV + carboplatin</td>
<td>TV weekly x 3 q28d</td>
</tr>
</tbody>
</table>

Completed enrollment 2021
Prespecified AEs of Special Interest

GOG 3024/innovaTV 205
IGCS 2021

GOG 3023/innovaTV 204

Monk et.al Virtual IGCS 2021

Coleman RL. Lancet Oncol. 2021:S1470-2045(21).
# Summary of Efficacy & Safety for 1L TV + Carbo

<table>
<thead>
<tr>
<th>Parameters</th>
<th>1L TV + Carbo (N = 33)</th>
<th>Median FU: 7.9 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median duration of exposure, months (range)</td>
<td>TV: 4.9 (1 - 9)</td>
<td>Carbo: 4.1 (1 - 9)</td>
</tr>
<tr>
<td>Median number of cycles initiated (range)</td>
<td>TV: 6.0 (1 - 12)</td>
<td>Carbo: 6.0 (1 - 12)</td>
</tr>
<tr>
<td>Confirmed response rate, n (%) [95% CI]</td>
<td>Complete response, n (%)</td>
<td>Partial response, n (%)</td>
</tr>
<tr>
<td></td>
<td>18 (55) [36 - 72]</td>
<td>4 (12)</td>
</tr>
<tr>
<td>Median duration of response, months (95% CI)</td>
<td>8.3 (4.2 - NR)</td>
<td></td>
</tr>
<tr>
<td>Median time to response, months (range)</td>
<td>1.4 (1.1 - 4.4)</td>
<td></td>
</tr>
<tr>
<td>Median PFS, months (95% CI)</td>
<td>9.5 (4.0 - NR)</td>
<td></td>
</tr>
<tr>
<td>Median OS, months (range)</td>
<td>NR (0.8+ - 14.1+)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameters</th>
<th>TV + Carbo (N=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with ≥1 TEAE, n (%)</td>
<td>33 (100.0)</td>
</tr>
<tr>
<td>AE related to TV</td>
<td>32 (97.0)</td>
</tr>
<tr>
<td>Grade ≥3 AE, n (%)</td>
<td>26 (78.8)</td>
</tr>
<tr>
<td>Grade ≥3 AE related to TV</td>
<td>19 (57.6)</td>
</tr>
<tr>
<td>SAE, n (%)</td>
<td>14 (42.4)</td>
</tr>
<tr>
<td>SAE related to TV</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td>Fatal AE, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Fatal AE related to TV</td>
<td>0</td>
</tr>
</tbody>
</table>

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**Legend:**
- **Grade 1/2 AESI**
- **Grade 3 AESI**

**Proportion of patients, %**

**Ocular**
- Grade 1/2: 60%
- Grade 3: 40%

**Bleeding**
- Grade 1/2: 40%
- Grade 3: 20%

**PN**
- Grade 1/2: 20%
- Grade 3: 10%

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Vergote I., et al.  
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1L: frontline; AE: adverse event; AESI: adverse event of special interest; carbo: carboplatin; FU: follow-up; NR: not reached; CRR: objective response rate; OS: overall survival; PFS: progression-free survival; PN: peripheral neuropathy; r/mCC: recurrent/metastatic cervical cancer; SAE: serious adverse event; TEAE: treatment-emergent adverse event; TV: taxol/nab-paclitaxel.
Summary of Efficacy & Safety for 2L/3L TV + Pembro

<table>
<thead>
<tr>
<th>Parameters</th>
<th>2L/3L TV + Pembro (N = 34)* Median FU: 13.0 months</th>
<th>TV + Pembro (N = 35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median duration of exposure, months (range)</td>
<td>TV: 4.1 (1 – 16)  Pembro: 4.3 (1 – 17)</td>
<td>Patients with ≥1 TEAE, n (%)</td>
</tr>
<tr>
<td>Median number of cycles initiated (range)</td>
<td>TV: 8.0 (1 – 21)  Pembro: 6.0 (1 – 25)</td>
<td>35 (100.0)</td>
</tr>
<tr>
<td>Confirmed response rate, n (%) [95% CI]</td>
<td></td>
<td>Grade ≥3 AE, n (%)</td>
</tr>
<tr>
<td>Complete response, n (%)</td>
<td>13 (38) [22 – 56]</td>
<td>16 (45.7)</td>
</tr>
<tr>
<td>Partial response, n (%)</td>
<td>2 (6)</td>
<td>18 (51.4)  SAE, n (%)</td>
</tr>
<tr>
<td>Stable Disease, n (%)</td>
<td>11 (32)</td>
<td>5 (14.3)  SAE related to TV</td>
</tr>
<tr>
<td>Progressive disease, n (%)</td>
<td>12 (35)</td>
<td>0</td>
</tr>
<tr>
<td>Not evaluable, n (%)</td>
<td>7 (21)</td>
<td>1 (2.9)  Fatal AE, n (%)</td>
</tr>
<tr>
<td>Median DOR, months (95% CI)</td>
<td>13.8 (2.8 – NR)</td>
<td>Fatal AE related to TV</td>
</tr>
<tr>
<td>Median time to response, months (range)</td>
<td>1.4 (1.3 – 5.8)</td>
<td>0</td>
</tr>
<tr>
<td>Median PFS, months (95% CI)</td>
<td>5.6 (2.7 – 13.7)</td>
<td></td>
</tr>
<tr>
<td>Median OS, months (range)</td>
<td>NR (1.3 – 17.5+)*</td>
<td></td>
</tr>
</tbody>
</table>

*1 pt was excluded from the full analysis set as they didn’t have any large or non-target lesions at baseline. Treatment ongoing in 4 patients.

Vergote I., et al.

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- TV: chemotherapy, 1L: first-line; AE: adverse event; AESI: adverse event of special interest; DOR: duration of response; FU: follow-up; NR: not reached; ORR: objective response rate; OS: overall survival; Pembro: pembrolizumab; PFS: progression-free survival; PN: peripheral neuropathy; r/mCC: recurrent/metastatic cervical cancer; SAE: serious adverse event; TEAE: treatment-emergent adverse event; TV: taxotere vadolin.
GOG 3016/ENGOT-cx9: Randomized Phase III Trial of Cemiplimab Versus Investigator’s Choice Chemotherapy in Cervical Cancer: “EMPOWER- CERVICAL 1” NCT03257267

Metastatic cervical cancer resistant to platinum-based chemotherapy, ≥ Second-Line (N = 436) ECOG PS 0 or 1

Primary Endpoint is OS

Statistical Considerations for Study Design
- Power: 90%
- Median Survival: 7 months
- Hazard Ratio: 0.7
- Timing of Final Analysis (Ha): 30.5 months

Cemiplimab 350 mg IV every 3 weeks

Accrual completed 5/29/2020
Overall survival

*Stratified by geographic region (North America vs Asia vs ROW) and Histology (SCC vs AC) according to interactive web response system. ††From randomisation to data cutoff date.

AC, adenocarcinoma or adenosquamous carcinoma; CI, confidence interval; HR, hazard ratio; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma.

HR (95% CI) = 0.69 (0.56–0.84)*
†one-sided \( P=0.00011 \)

Cemiplimab
Chemotherapy

Overall Population

Median duration of follow-up†: 18.2 months (range: 6.0–38.2)

No. of patients
Median OS (95% CI), mo
Cemiplimab 304 12.0 (95% CI, 10.3–13.5)
Chemotherapy 304 8.5 (95% CI, 7.5–9.6)

Tewari KS et al. Virtual Interim ESMO 2021

Data cutoff date: 4 Jan 2021

No. at risk:
Cemiplimab
Chemotherapy

Month
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36

Median OS (95% CI), mo
Chemotherapy 304 8.5 (95% CI, 7.5–9.6)
Cemiplimab 304 12.0 (95% CI, 10.3–13.5)

Probability of survival

Month
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36

No. of patients

Chemotherapy

Cemiplimab

No. at risk:
Cemiplimab 304 281 236 206 167 139 110 83 65 52 35 26 13 10 9 4 2 2 0
Chemotherapy 304 264 224 183 132 99 70 54 32 22 15 12 9 5 3 2 1 0 0
Survival analysis by PD-L1 status*

*Associations between efficacy outcomes and PD-L1 expression (detected using the SP263 monoclonal antibody) in tumor cells was evaluated using exploratory analyses. Of 608 randomized patients, 254 had valid baseline PD-L1 samples: cemiplimab (n=126) and chemotherapy (n=128).

Data cutoff date: 4 Jan 2021.

PD-L1, programmed cell death-ligand 1; TC, tumor cells.

Krishnansu S Tewari
Balstilimab (anti-PD-1) in combination with zalifrelimab (anti-CTLA-4): final results from a Phase 2 study in patients (pts) with recurrent/metastatic (R/M) cervical cancer (CC)

D.M. O’Malley¹, M. Neffa², B.J. Monk³, T. Melkadze⁴, A. Kryzhanivska⁵, I. Bulat⁶, T.M. Meniawy⁷, I. Bondarenko⁸, W. Ortuzar Feliu⁹, M. Ancukiewicz⁹, I. Lugowska¹⁰

¹Division of Gynecologic Oncology, The Ohio State University/James Comprehensive Cancer Center, Columbus, Ohio; ²Department of Surgery, CI of Healthcare Regional Clinical Specialized Dispensary of the Radiation Protection, Kharvik, Ukraine; ³Arizona Oncology (US Oncology Network), University of Arizona College of Medicine, Creighton University School of Medicine, Phoenix, Arizona; ⁴Medical Oncology, Research Institute of Clinical Medicine, Tbilisi, Georgia; ⁵Regional Clinical Oncology Center, Ivano-Frankivsk National Medical University, Ivano-Frankivsk, Ukraine; ⁶ARENSIA Exploratory Medicine, Institute of Oncology Unit, Chisinau, Moldova; ⁷Linear Clinical Research, Nedlands, Australia; ⁸Department of Chemotherapy, Dnipropetrovsk Medical Academy of Ministry of Health of Ukraine, Dnipropetrovsk, Ukraine; ⁹Clinical Development, Agenus Inc., Lexington, Massachusetts; ¹⁰Department of Soft Tissue/Bone Sarcoma and Melanoma, Maria Sklodowska-Curie Memorial Cancer Center, Warsaw, Poland.
Clinical Activity

<table>
<thead>
<tr>
<th>ORR, N (%)</th>
<th>32 (25.6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>10 (8.0)</td>
</tr>
<tr>
<td>PR</td>
<td>22 (17.6)</td>
</tr>
<tr>
<td>PD-L1+ (n = 67)</td>
<td>22 (32.8)</td>
</tr>
<tr>
<td>PD-L1- (n = 33)</td>
<td>3 (9.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOR, months [range]</th>
<th>NR [9.3, NR]</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 month (%)</td>
<td>86.5</td>
</tr>
<tr>
<td>12 month (%)</td>
<td>64.2</td>
</tr>
</tbody>
</table>
Kaplan-Meier Survival Estimates

Median duration of follow-up: 21 months

PFS

mPFS 2.7 mo (95% CI, 1.5-3.7)

OS

mOS 12.8 mo (95% CI, 8.8-17.6)

PD-L1+ subset mOS: 15.7 mo (95% CI, 7.6, 21.1)
**GOG-3028 - A Two Arm, Randomized, Non Comparative Blinded Phase 2 Trial of Balstilimab +/- Zalifrelimab in Second Line Cervical Cancer**

**Patient Eligibility**
- Cervical cancer that has relapsed after a platinum-based treatment (first line) regimen for advanced (recurrent, unresectable, or metastatic) disease
- Measurable disease on imaging based on RECIST version 1.1
- ECOG PS ≤1
- Sufficient and adequate formalin-fixed paraffin embedded (FFPE)

**RaPiDS**
Treatment up to 24 months

- Balstilimab (300 mg) every 3 weeks, Placebo every 6 weeks
- Balstilimab (300 mg) every 3 weeks, Zalifrelimab (1 mg/kg) every 6 weeks

**Primary Endpoint**
- ORR according to RECIST 1.1
Cervical Cancer: Projected Treatment Landscape

- **Locally Advanced Disease**
  - Chemoradio(immuno)therapy
  - KEYNOTE A18/ENGOT cx11/GOG 3047

- **Metastatic Disease**
  - **PDL1+**
    - KEYNOTE 826
  - **PDL1-**
    - GOG 240
Cervical Cancer: Projection of Treatment

2nd Line

No Prior IO
- GOG 3028/RaPiDs
- Pembro/nivo (PDL1+)
- Tisotumab Vedotin
- LN-145 (lifileucel) TILs?
- URGENT NEED non-IO, post-IO options

Prior IO
- Tisotumab Vedotin
- LN-145 (lifileucel) TILs?
- URGENT NEED non-IO, post-IO options

I/O combos?
- Clinical trial
- Assay-directed
- Chemotherapy

URGENT NEED non-IO, post-IO options