
Domenica Lorusso,1 Yang Xiang,2 Kosei Hasegawa,3 Giovanni Scambia,4 Manuel Leiva,5 Pier Ramos-Elias,6 Alejandro Acevedo,7 Julia Vizkeleti,8 Andrea Gomes,9 Fernando Conteras Mejía,10 Ari Reiss,11 Ali Ayhan,12 Jung-Yun Lee,13 Valeriya Saevets,14 Flora Zagouri,15 Kan Li,16 Karin Yamada,16 Sarper Toker,16 Sandro Pignata,17 Linda R. Duska18 on behalf of the ENGOT-cx11/GOG-3047/KEYNOTE-A18 investigators

1Gynaecology Oncology Unit, Fondazione Policlinico Universitario A Gamelli IRCCS and Catholic University of Sacred Heart, Rome, Italy; 2Department of Obstetrics and Gynecology, Peking Union Medical College Hospital, National Clinical Research Center for Obstetric & Gynecologic Diseases, Beijing, China; 3Saitama Medical University International Medical Center, Hidaka, Saitama, Japan; 4Scientific Directorate, Fondazione Policlinico Universitario Agostino Gemelli IRCCS and Catholic University of the Sacred Heart, Rome, Italy; 5Instituto de Oncologia y Radioterapia Clinica Ricardo Palma, Lima, Peru; 6Integra Cancer Institute, Edificio Integra Medical Center, Guatemala City, Guatemala; 7Oncocentro, Valparaíso, Chile; 8National Institute of Oncology, Centre of Radiotherapy, Budapest, Hungary; 9Liga Norte Riograndense Contra o Cancer Rio Grande do Norte, Brazil; 10Instituto Nacional de Cancerología, Bogota, Colombia; 11Rambam Medical Center, Gyneco-oncology Unit, Haifa, Israel; 12Turkish Society of Gynecologic Oncology (TRSGO), Başkent University, Ankara, Turkey; 13Severance Hospital, Yonsei University College of Medicine, Seoul, Republic of Korea; 14Chelyabinsk Regional Clinical Center Oncology and Nuclear Medicine, Chelyabinsk, Russia; 15Alexandra Hospital, Athens, Greece; 16Merck & Co., Inc., Rahway, NJ, USA; 17Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Napoli, Italy; 18University of Virginia School of Medicine, Charlottesville, VA, USA

*Drs. Pignata and Duska contributed equally to this presentation.
Declaration of Interests

• Domenica Lorusso
  – Honoraria: AstraZeneca, Clovis, Genmab, Immunogen, Merck & Co., Inc., Roche, Tesaro
  – Consulting or Advisory Role: PharmaMar
  – Speakers' Bureau: AstraZeneca, Clovis, PharmaMar, Tesaro
  – Research Funding: Clovis (Inst), Merck (Inst), PharmaMar (Inst), Tesaro (Inst)
  – Expert Testimony: Clovis
  – Travel, Accommodations, Expenses: AstraZeneca, Clovis, PharmaMar, Roche, Tesaro

• Study funding, medical writing, and editorial support: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA
Background

• Since 1999, standard therapy for patients with locally advanced cervical cancer has been represented by external beam radiotherapy with concurrent chemotherapy followed by brachytherapy.  
1-3

• Preclinical and clinical data suggest that the effect of chemoradiotherapy may be enhanced by immunotherapy4

• The PD-1 inhibitor pembrolizumab has shown efficacy and a manageable safety profile in patients with cervical cancer
  – In the phase 2 KEYNOTE-158 study: 14.3% ORR in patients with ≥1 prior line of chemotherapy and PD-L1–positive recurrent or metastatic cervical cancer5
  – In the phase 3 KEYNOTE-826 study: statistically significant and clinically meaningful PFS and OS improvements in patients with persistent, recurrent, or metastatic cervical cancer with the addition of pembrolizumab to platinum-based chemotherapy ± bevacizumab6,7

• In the phase 3 ENGOT-cx11/GOG-3047/KEYNOTE-A18 study, we assessed the efficacy and safety of pembrolizumab + concurrent chemoradiotherapy for patients with high-risk, locally advanced cervical cancer  

ENGOT-cx11/GOG-3047/KEYNOTE-A18: Randomized, Double-Blind, Phase 3 Study

Key Eligibility Criteria
- FIGO 2014 stage IB2-IIB (node-positive disease) or FIGO 2014 stage III-IVA (either node-positive or node-negative disease)
- RECIST 1.1 measurable or non-measurable disease
- Treatment naïve

Stratification Factors
- Planned EBRT type (IMRT or VMAT vs non-IMRT or non-VMAT)
- Stage at screening (stage IB2-IIB vs III-IVA)
- Planned total radiotherapy dose (<70 Gy vs ≥70 Gy [EQ2D])

Cisplatin 40 mg/m² QW for 5 cycles\(^a\) + EBRT followed by brachytherapy
+ Pembrolizumab 200 mg Q3W for 5 cycles

Pembrolizumab 400 mg Q6W for 15 cycles

Cisplatin 40 mg/m² QW for 5 cycles\(^a\) + EBRT followed by brachytherapy
+ Placebo Q3W for 5 cycles

Placebo Q6W for 15 cycles

\(^a\) A 6th cycle was allowed per investigator discretion. EBRT, external beam radiotherapy; FIGO, International Federation of Gynecology and Obstetrics; Gy, grays; IMRT, intensity-modulated radiotherapy; Q3W, every 3 weeks; Q6W, every 6 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; VMAT, volumetric-modulated arc therapy. ENGOT-cx11/GOG-3047/KEYNOTE-A18 ClinicalTrials.gov identifier, NCT04221945.

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

Presented by: Domenica Lorusso
Study End Points and Milestones

**End Points**

- **Primary:** PFS (per RECIST v1.1) by investigator or histopathologic confirmation and OS
- **Key secondary:** 24-month PFS, ORR, patient-reported outcomes, and safety

---

**First participant randomized**
[09-Jun-2020]

**Protocol amendment 1:** Change of primary end point from PFS by BICR to PFS by investigator
[06-Jan-2021]

**Final protocol amendment:** Change of multiplicity strategy in the SAP
[08-Nov-2022]

**Last participant randomized**
[15-Dec-2022]

---

**Multiplicity**

- PFS
  - Initial one-sided $\alpha = 0.025$
- OS
  - Initial one-sided $\alpha = 0$

Prespecified analysis plan allows alpha from successful hypothesis to be passed to the other hypothesis.

---

BICR, blinded independent central review; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; SAP, statistical analysis plan.

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
Statistical Considerations

Protocol-specified first interim analysis (IA1)

- **Timing:** at completion of enrollment and when ~237 events (PD or death) had occurred
- **Objective:** to assess whether adding pembrolizumab to chemoradiotherapy significantly improves PFS and OS
- **Data cutoff date:** January 9, 2023
- **Interim analysis 1 database lock:** February 17, 2023
- **Median (range) follow-up** (defined as the time from randomization to the data cutoff date of January 9, 2023): 17.9 months (0.9-31.0)

Analysis populations

- **Efficacy:** all randomized participants
- **Safety:** all randomized participants who received ≥1 dose of study drug
Treatment Disposition

1562 participants entered screening
1060 participants randomly allocated at 176 sites in 30 countries

32% screening failure

Pembrolizumab + Chemoradiotherapy
- 529 allocated
- 528 treated
- 305 (57.8%) continued treatment
- 58 (11.0%) completed treatment
- 165 (31.3%) discontinued treatment
  - 84 radiographic progression
  - 45 adverse event
  - 21 withdrawal of consent
  - 4 physician decision
  - 2 non-compliance
  - 2 progressive disease
  - 1 excluded medication
  - 1 protocol violation

Placebo + Chemoradiotherapy
- 531 allocated
- 530 treated
- 291 (54.9%) continued treatment
- 56 (10.6%) completed treatment
- 183 (34.5%) discontinued treatment
  - 122 radiographic progression
  - 18 adverse event
  - 24 withdrawal of consent
  - 8 clinical progression
  - 4 physician decision
  - 1 non-compliance
  - 5 progressive disease
  - 1 lost to follow-up

*Defined as histopathological progression.

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Pembro Arm (N = 529)</th>
<th>Placebo Arm (N = 531)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, median (range)</strong></td>
<td>49 y (22-87)</td>
<td>50 y (22-78)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>254 (48.0%)</td>
<td>264 (49.7%)</td>
</tr>
<tr>
<td>Asian</td>
<td>155 (29.3%)</td>
<td>148 (27.9%)</td>
</tr>
<tr>
<td>Multiple</td>
<td>78 (14.7%)</td>
<td>86 (16.2%)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>24 (4.5%)</td>
<td>22 (4.1%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>14 (2.6%)</td>
<td>8 (1.5%)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>2 (0.4%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td><strong>PD-L1 CPS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>22 (4.2%)</td>
<td>28 (5.3%)</td>
</tr>
<tr>
<td>≥1</td>
<td>502 (94.9%)</td>
<td>498 (93.8%)</td>
</tr>
<tr>
<td>Missing</td>
<td>5 (0.9%)</td>
<td>5 (0.9%)</td>
</tr>
<tr>
<td><strong>ECOG PS 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>149 (28.2%)</td>
<td>134 (25.2%)</td>
</tr>
<tr>
<td></td>
<td>433 (81.9%)</td>
<td>451 (84.9%)</td>
</tr>
<tr>
<td><strong>Stage at screening (FIGO 2014 criteria)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IB2-IIB</td>
<td>235 (44.4%)</td>
<td>227 (42.7%)</td>
</tr>
<tr>
<td>III-IVA</td>
<td>294 (55.6%)</td>
<td>304 (57.3%)</td>
</tr>
<tr>
<td><strong>Lymph node involvement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive pelvic only</td>
<td>326 (61.6%)</td>
<td>324 (61.0%)</td>
</tr>
<tr>
<td>Positive para-aortic only</td>
<td>14 (2.6%)</td>
<td>10 (1.9%)</td>
</tr>
<tr>
<td>Positive pelvic and para-aortic</td>
<td>105 (19.8%)</td>
<td>104 (19.6%)</td>
</tr>
<tr>
<td>No positive pelvic or para-aortic</td>
<td>84 (15.9%)</td>
<td>93 (17.5%)</td>
</tr>
<tr>
<td><strong>Planned type of EBRT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMRT or VMAT</td>
<td>469 (88.7%)</td>
<td>470 (88.5%)</td>
</tr>
<tr>
<td>Non-IMRT and non-VMAT</td>
<td>60 (11.3%)</td>
<td>61 (11.5%)</td>
</tr>
<tr>
<td><strong>Planned total radiotherapy dose (EQD2)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 Gy</td>
<td>47 (8.9)</td>
<td>46 (8.7)</td>
</tr>
<tr>
<td>≥70 Gy</td>
<td>482 (91.1%)</td>
<td>485 (91.3%)</td>
</tr>
</tbody>
</table>

*In each treatment arm, 2 patients (0.4%) had missing information for race.*

*Per protocol, a positive lymph node is defined as ≥1.5 cm shortest dimension by MRI or CT. Data cutoff date: January 9, 2023.*

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
## Summary of Treatment Exposure

<table>
<thead>
<tr>
<th></th>
<th>Pembro Arm (N = 528)</th>
<th>Placebo Arm (N = 530)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total number of cycles, median (range)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pembro or placebo</td>
<td>11 (1-20)</td>
<td>11 (1-20)</td>
</tr>
<tr>
<td>Cisplatin&lt;sup&gt;a&lt;/sup&gt;</td>
<td>5 (1-7)</td>
<td>5 (1-7)</td>
</tr>
<tr>
<td><strong>Radiation therapy, median (range)&lt;sup&gt;a&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall treatment time (days)</td>
<td>52 (12-139)</td>
<td>52 (2-166)</td>
</tr>
<tr>
<td>Within 50 days&lt;sup&gt;b&lt;/sup&gt;, n (%)</td>
<td>184 (35.5%)</td>
<td>194 (37.2%)</td>
</tr>
<tr>
<td>Within 56 days, n (%)</td>
<td>386 (74.5%)</td>
<td>390 (74.7%)</td>
</tr>
<tr>
<td><strong>Cervix total dose (Gy), median (range)&lt;sup&gt;a&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cervix physical dose</td>
<td>76 (14-94)</td>
<td>76 (3-125)</td>
</tr>
<tr>
<td>Total cervix EQD2 dose</td>
<td>87 (14-118)</td>
<td>87 (3-207)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Includes participants who completed concurrent chemoradiotherapy at this interim analysis and had final data review by the vendor (pembro arm N=518; placebo arm N=522).

<sup>b</sup>Total radiation therapy (EBRT and brachytherapy) should not exceed 50 days, with extension to a maximum of 56 days for unforeseen delays, as per the study protocol. Data cutoff date: January 9, 2023.
Primary Endpoint: Progression-Free Survival

HR 0.70 (95% CI, 0.55-0.89)  
*P* = 0.0020a

Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation. aWith 269 events (88.5% information fraction), the observed *P* = 0.0020 (1-sided) crossed the prespecified nominal boundary of 0.0172 (1-sided) at this planned first interim analysis. The success criterion of the PFS hypothesis was met, and thus no formal testing of PFS will be performed at a later analysis. Data cutoff date: January 9, 2023.

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
### Progression-Free Survival: Protocol-Specified Subgroups

<table>
<thead>
<tr>
<th></th>
<th>No. of Events/No. of Patients</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>269/1060</td>
<td>0.70 (0.55-0.89)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>236/927</td>
<td>0.72 (0.56-0.94)</td>
</tr>
<tr>
<td>≥65 years</td>
<td>33/133</td>
<td>0.57 (0.27-1.17)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>143/518</td>
<td>0.83 (0.59-1.15)</td>
</tr>
<tr>
<td>All others</td>
<td>125/538</td>
<td>0.60 (0.42-0.86)</td>
</tr>
<tr>
<td><strong>ECOG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>197/777</td>
<td>0.79 (0.59-1.04)</td>
</tr>
<tr>
<td>1</td>
<td>72/283</td>
<td>0.53 (0.33-0.85)</td>
</tr>
<tr>
<td><strong>Planned type of EBRT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMRT/VMAT</td>
<td>237/939</td>
<td>0.68 (0.52-0.87)</td>
</tr>
<tr>
<td>non-IMRT/-VMAT</td>
<td>32/121</td>
<td>0.92 (0.46-1.85)</td>
</tr>
<tr>
<td><strong>FIGO 2014 stage at screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IB2 to IIB</td>
<td>113/462</td>
<td>0.91 (0.63-1.31)</td>
</tr>
<tr>
<td>III to IVA</td>
<td>156/598</td>
<td>0.58 (0.42-0.80)</td>
</tr>
<tr>
<td><strong>Planned total radiotherapy dose</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 Gy</td>
<td>25/93</td>
<td>0.62 (0.28-1.38)</td>
</tr>
<tr>
<td>≥70 Gy</td>
<td>244/967</td>
<td>0.71 (0.55-0.91)</td>
</tr>
</tbody>
</table>

Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation.

Data cutoff date: January 9, 2023.

Presented by: Domenica Lorusso
Primary Endpoint: Overall Survival

HR 0.73 (95% CI, 0.49-1.07)

Overall Survival, %

Median (range) follow-up: 17.9 mo (0.9-31.0)

24-mo rate (95% CI)

87.2% (82.4-90.8)
80.8% (74.8-85.5)

No. at risk

Time, months

0 3 6 9 12 15 18 21 24 27 30 33

529 496 456 405 351 294 223 151 67 10 1 0
531 498 449 402 339 278 214 139 62 12 0 0

Pts w/ Event* Median, mo (95% CI)

Pembro Arm 8.3% NR (NR-NR)
Placebo Arm 11.1% NR (NR-NR)

*42.9% information fraction

At this analysis, 103 of the 240 deaths expected at the final analysis had occurred.

Data cutoff date: January 9, 2023.

Presented by: Domenica Lorusso
Secondary End Points: Best Objective Response and Duration of Response

Response assessed per RECIST v1.1 by investigator review.
Data cutoff date: January 9, 2023.

CR: 50.7%
PR: 28.6%
CR: 48.7%
PR: 27.2%

Δ 3.4
(-1.7 to 8.5)

12-mo rate
81.4%
77.3%

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
# Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>All-Cause AEs</th>
<th>Treatment-Related AEs&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Immune-Mediated AEs&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pembro Arm (N = 528)</td>
<td>Placebo Arm (N = 530)</td>
<td>Pembro Arm (N = 528)</td>
</tr>
<tr>
<td>Any grade</td>
<td>525 (99.4%)</td>
<td>526 (99.2%)</td>
<td>507 (96.0%)</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>394 (74.6%)</td>
<td>364 (68.7%)</td>
<td>354 (67.0%)</td>
</tr>
<tr>
<td>Serious</td>
<td>150 (28.4%)</td>
<td>131 (24.7%)</td>
<td>91 (17.2%)</td>
</tr>
<tr>
<td>Led to death</td>
<td>5 (0.9%)</td>
<td>6 (1.1%)</td>
<td>2 (0.4%)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Led to discontinuation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any treatment</td>
<td>92 (17.4%)</td>
<td>75 (14.2%)</td>
<td>81 (15.3%)</td>
</tr>
<tr>
<td>All treatment</td>
<td>1 (0.2%)</td>
<td>2 (0.4%)</td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>a</sup>Per investigator assessment.  
<sup>b</sup>Events were considered regardless of attribution to treatment by the investigator.  
<sup>c</sup>Immune-mediated gastritis and large intestine perforation.  
<sup>d</sup>Bone marrow failure and neutropenic colitis.  
Data cutoff date: January 9, 2023.
Treatment-Related AEs, Incidence ≥20% in Either Arm

- Anemia
- Nausea
- Diarrhea
- WBC count decreased
- Neutrophil count decreased
- Vomiting
- Leukopenia
- Platelet count decreased
- Neutropenia

Data cutoff date: January 9, 2023.

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
Immune-Mediated AEs, Incidence ≥2 Patients in Either Arm

- Hypothyroidism: 19.3%
- Hyperthyroidism: 11.4%
- Colitis: 4.5%
- Thyroiditis: 2.1%
- Pneumonitis: 2.1%
- Severe skin reactions: 0.2%
- Adrenal insufficiency: 0.2%
- Nephritis: 0.4%

Events were considered regardless of attribution to treatment by the investigator. Related terms were included in addition to the specific terms listed.

Data cutoff date: January 9, 2023.

Presented by: Domenica Lorusso
EORTC Quality-of-Life Core 30 (QLQ-C30)

- Administered at each treatment cycle
- Compliance at week 36: 96.0% for both pembrolizumab and placebo arms
- Analysis population: all treated participants with ≥1 available PRO assessment
- No clinically meaningful between-group differences in changes in score from baseline to week 36 were observed for QLQ-C30 global health status/QoL or QLQ-C30 physical functioning scores

EORTC QLQ-C30 Global Health Status/QoL

Weeks
0  3  6  9  12  18  24  30  36  42  48  54  60  66  72  78  84  90  96  102  114

Mean Score Change from Baseline (95% CI)

Between-group difference in change from baseline to week 36 (95% CI): 0.57 (-2.34 to 3.49)

Compliance was defined as the proportion of participants who completed the questionnaire among those who were expected to complete the questionnaire at the time point, excluding those missing by design such as death, discontinuation, or translation not available. Data cutoff date: January 9, 2023.

No. of participants
Pembro Arm Placebo Arm
475 446 409 409 402 411 355 335 300 275 257 226 210 176 173 143 126 107 83 58 19
482 452 414 412 405 414 356 321 293 268 245 219 206 178 165 140 116 94 66 50 18

Presented by: Domenica Lorusso
Summary and Conclusions

- Pembrolizumab combined with chemoradiotherapy and then continued after chemoradiotherapy provided statistically significant and clinically meaningful improvements in progression-free survival versus chemoradiotherapy alone in patients with newly diagnosed, previously untreated, high-risk, locally advanced cervical cancer
  - Benefit generally consistent across all protocol-specified subgroups
  - High-quality radiotherapy delivery was ensured
- At this first interim analysis, the estimate of effect on overall survival supports the progression-free survival results
- Objective response rate and duration of response rate (point estimates) were higher with the addition of pembrolizumab
- Safety profile for pembrolizumab plus chemoradiotherapy was manageable and as expected
- There was no negative impact on patient-reported outcomes with the addition of pembrolizumab
- These data support pembrolizumab plus chemoradiotherapy as a new potential standard of care for patients with newly diagnosed, previously untreated, high-risk, locally advanced cervical cancer

Presented by: Domenica Lorusso

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.
PATIENTS AND THEIR FAMILIES
The ENGOT, GOG, and all investigators and site personnel from 176 sites in 30 countries who participated in this study

All personnel of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA who supported the study, particularly Gursel Aktan (study oversight), Stephen M. Keefe (study leadership), Martina Puglisi, Susan Galligan, Amy Blum, Eleanor Readinger, and Jacqueline Whetteckey (collection of data, supervision of research, document review), Jing Zhao (statistical expertise), Elizabeth Szamreta, and Allison Martin Nguyen (patient-reported outcomes), and Christine McCratty Sisk, and Michele McColgan (editorial assistance).

Copies of this presentation obtained via QR code/Web link are for personal use only and may not be reproduced without permission from ESMO and the authors. Requesting content via the QR code or Web link will immediately download the requested content to your device. This presentation is intended as an educational resource and is for the exchange of scientific data to clinical investigators and health care professionals.