Primary results from BEATcc (ENGOT-Cx10/ GEICO 68-C/JGOG1084/GOG-3030), a randomised phase 3 trial of first-line atezolizumab combined with bevacizumab and a platinum doublet for metastatic (stage IVB), persistent or recurrent cervical cancer

Ana Oaknin

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On behalf of L Gladieff (GINECO, France), J Martínez-García (GEICO, Spain), G Villacampa (Spain), M Takekuma (JGOG, Japan), U De Giorgi (MITO, Italy), K Lindemann (NSGO-CTU, Norway), L Woelber (AGO, Germany), N Colombo (MaNGO, Italy), L Duska (GOG-F, USA), A Leary (GINECO), A Godoy-Ortiz (GEICO), S Nishio (JGOG), A Angelergues (GINECO), M Jesús Rubio (GEICO), L Fariñas-Madrid (GEICO), S Yamaguchi (JGOG), D Lorusso (MITO), V D’Hondt (GINECO) and LM Randall (GOG-F)
Declaration of interests

Ana Oaknin

• Personal fees for advisory boards: AstraZeneca, Clovis Oncology, Deciphera, Genmab, GSK, Immunogen, Mersana Therapeutics, PharmaMar, MSD de España SA, Agenus, Sutro, Corcept Therapeutics, EMD Serono, Novocure, Shattuck Labs, iTeos, Eisai

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• Non-financial interests: Gynaecological Track Chair ESMO 2019; Scientific Track Member Gynaecological Cancers ESMO 2018, 2020, 2022, 2023, 2024; member of Gynaecological Cancers Faculty and Subject Editor GYN ESMO Guidelines; ESMO GYN Co-Chair 2022–2025; GCIG Cervix Committee Chair 2022–2024, member of ESMO, ASCO, GCIG, SEOM, GOG
Background

Rationale for combining immune checkpoint blockade, bevacizumab and chemotherapy

- 2014: GOG 240 demonstrated significantly improved OS (median 17.5 months) with bevacizumab (anti-VEGF) added to platinum-based chemotherapy in patients with R/M CC
  - Preferred first-line therapy for R/M CC
- 2021: KEYNOTE-826 demonstrated significantly improved PFS and OS with pembrolizumab (anti-PD-1) added to platinum-based chemotherapy (optional bevacizumab) for R/M CC
  - Median OS: 26.4 months in all-comers
- Both VEGF and PD-L1 are relevant in cervical cancer pathogenesis
  - Peripheral immune tolerance and angiogenesis are closely connected and cooperate to sustain tumour growth
  - Inhibiting both immunosuppression and angiogenesis may result in improved and more durable clinical benefit
- 2023: BEATcc is the first global phase 3 trial evaluating atezolizumab (anti-PD-L1) added to mandatory bevacizumab and platinum-based chemotherapy for R/M CC

GOG = Gynecologic Oncology Group; OS = overall survival; PFS = progression-free survival; PD-1 = programmed death 1; PD-L1 = programmed death ligand 1; R/M CC = metastatic, persistent or recurrent cervical cancer; VEGF = vascular endothelial growth factor

**BEATcc trial design (NCT03556839)**

Open-label, multicentre, randomised, phase 3 trial in an all-comer population

- Metastatic, persistent or recurrent cervical cancer not amenable to curative therapy
- GOG/ECOG PS ≤1
- No prior systemic anti-cancer therapy for R/M CC
- In patients with pelvic disease, no bladder or rectal mucosa involvement
- Available archival or fresh tumour sample for PD-L1 expression

**Stratification factors:**
- Prior concurrent chemoradiation (yes vs no)
- Histology (squamous cell carcinoma vs adenocarcinoma\(^b\) including adenosquamous carcinoma)
- Chemotherapy backbone (cisplatin vs carboplatin)

---

**Atezolizumab 1200 mg + bevacizumab 15 mg/kg + paclitaxel + cis/carboplatin\(^a\)**
- Continued until disease progression/unacceptable toxicity
- Patients with CR after ≥6 cycles could stop chemotherapy and continue biological therapy alone
- Crossover from standard arm at progression not permitted

**Bevacizumab 15 mg/kg + paclitaxel + cis/carboplatin\(^a\)**

---

**Dual primary endpoints**
- Investigator-assessed PFS (RECIST 1.1)
- OS

**Key secondary endpoints**
- ORR (RECIST v1.1)
- DoR (RECIST v1.1)
- TFST
- PFS2
- Safety

---

\(^a\)Paclitaxel 175 mg/m\(^2\) day 1 + platinum (cisplatin 50 mg/m\(^2\) or carboplatin AUC5) day 1; \(^b\)Capped at 20% of the overall population

CR = complete response; DoR = duration of response; ECOG = Eastern Cooperative Oncology Group; ORR = objective response rate; PFS2 = time from randomisation to second progression or death; PS = performance status; q3w = every 3 weeks; TFST = time from randomisation to first subsequent therapy or death

---

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**Statistical analysis plan**

**Dual primary endpoint analysis**

- Prespecified analysis after $\geq$280 PFS events
- Two-sided stratified log-rank test, 80% power
- Target HR: $\sim$0.675 for PFS and 0.70 for interim OS

2018  | 2019  | 2020  | 2021  | 2022  | 2023  \\
--- | --- | --- | --- | --- | ---  \\

- PFS $\alpha = 0.02$
  - 280 PFS events

- Interim OS $\alpha \approx 0.013$
  - ($\approx 0.0238$ if PFS positive)

- Final OS
  - 292 OS events

- Overall $a = 0.05$
  - If one positive and one negative, $\alpha$ recycled

OS $\alpha = 0.03$

*HR = hazard ratio*

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Patient disposition

Median follow-up: 32.9 months (95% CI 31.2–34.6 months)

410 patients randomised

206 allocated to atezolizumab + bevacizumab + CT
- 205 received allocated intervention
- 1 did not receive allocated intervention

47 still receiving at least one treatment
159 discontinued all treatments/never started
- 110 disease progression (clinical/radiological)
- 20 adverse event
- 9 physician decision
- 12 consent withdrawal
- 6 death
- 2 other

204 allocated to bevacizumab + CT
- 199 received allocated intervention
- 5 did not receive allocated intervention

14 still receiving at least one treatment
190 discontinued all treatments/never started
- 116 disease progression (clinical/radiological)
- 38 adverse event
- 18 physician decision
- 12 consent withdrawal
- 2 death
- 4 other

Still in follow-up: 68 patients (33%) in the standard arm and 91 (44%) in the experimental arm

CT = chemotherapy

Ana Oaknin, MD, PhD
## Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic, n (%)</th>
<th>Atezo + bev + CT (n=206)</th>
<th>Bev + CT (n=204)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median (range) age, years</strong></td>
<td>51.0 (24–90)</td>
<td>52.5 (21–79)</td>
</tr>
<tr>
<td><strong>Age, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>171 (83)</td>
<td>168 (82)</td>
</tr>
<tr>
<td><strong>GOG/ECOG PS, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>138 (67)</td>
<td>128 (63)</td>
</tr>
<tr>
<td>1</td>
<td>68 (33)</td>
<td>73 (36)</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>111 (54)</td>
<td>113 (55)</td>
</tr>
<tr>
<td>Other</td>
<td>45 (22)</td>
<td>42 (21)</td>
</tr>
<tr>
<td>Not available</td>
<td>50 (24)</td>
<td>49 (24)</td>
</tr>
<tr>
<td><strong>Histology, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>164 (80)</td>
<td>157 (77)</td>
</tr>
<tr>
<td>Adenocarcinoma/adenosquamous carcinoma</td>
<td>42 (20)</td>
<td>47 (23)</td>
</tr>
<tr>
<td><strong>Disease status at screening, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metastatic (stage IVB)</td>
<td>43 (21)</td>
<td>47 (23)</td>
</tr>
<tr>
<td>Recurrent</td>
<td>150 (73)</td>
<td>151 (74)</td>
</tr>
<tr>
<td>Persistent</td>
<td>13 (6)</td>
<td>6 (3)</td>
</tr>
<tr>
<td><strong>Disease location at screening, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic and distant</td>
<td>102 (50)</td>
<td>90 (44)</td>
</tr>
<tr>
<td>Distant only</td>
<td>71 (34)</td>
<td>74 (36)</td>
</tr>
<tr>
<td>Pelvic only</td>
<td>33 (16)</td>
<td>40 (20)</td>
</tr>
<tr>
<td><strong>Primary therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concurrent chemoradiotherapy</td>
<td>70 (34)</td>
<td>85 (42)</td>
</tr>
<tr>
<td>Surgery followed by chemoradiotherapy</td>
<td>64 (31)</td>
<td>44 (22)</td>
</tr>
<tr>
<td>Surgery and/or radiotherapy</td>
<td>16 (8)</td>
<td>28 (14)</td>
</tr>
<tr>
<td>None</td>
<td>56 (27)</td>
<td>47 (23)</td>
</tr>
</tbody>
</table>

*Missing in three patients. ‡Asian (n=58), Latin (n=18), Arab (n=5), Black (n=5), Gypsy (n=1). ‡Per local legislation

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Dual primary endpoint: PFS

Statistically significant 38% reduction in risk of progression or death

<table>
<thead>
<tr>
<th></th>
<th>Atezo + bev + CT</th>
<th>Bev + CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events, n (%)</td>
<td>138 (67)</td>
<td>166 (81)</td>
</tr>
<tr>
<td>Stratified HR (95% CI)</td>
<td>0.62 (0.49–0.78); p&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>13.7 (12.3–16.6)</td>
<td>10.4 (9.7–11.7)</td>
</tr>
</tbody>
</table>

PFS probability

No. at risk

Atezo + bev + CT 206 174 114 79 58 37 13 5 1 1 0
Bev + CT 204 159 80 47 31 13 5 1 1 0

Data cut-off: 17 Jul 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months)
Dual primary endpoint: OS (interim analysis)

Statistically significant 32% reduction in risk of death

<table>
<thead>
<tr>
<th></th>
<th>Atezo + bev + CT</th>
<th>Bev + CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events, n (%)</td>
<td>105 (51)</td>
<td>129 (63)</td>
</tr>
<tr>
<td>Stratified HR (95% CI)</td>
<td>0.68 (0.52–0.88); p=0.0046a</td>
<td></td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>32.1 (25.3–36.8)</td>
<td>22.8 (20.3–28.0)</td>
</tr>
</tbody>
</table>

Data cut-off: 17 Jul 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months). aInterim OS was statistically significant, crossing the boundary of p=0.0238

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# PFS and OS in protocol-specified subgroups

## PFS

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>No. events/patients</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>304/410</td>
<td>0.62 (0.49–0.78)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>246/339</td>
<td>0.66 (0.51–0.85)</td>
</tr>
<tr>
<td>≥65</td>
<td>58/71</td>
<td>0.45 (0.26–0.78)</td>
</tr>
<tr>
<td>GOG/ECOG PS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>187/266</td>
<td>0.66 (0.49–0.87)</td>
</tr>
<tr>
<td>1</td>
<td>114/141</td>
<td>0.60 (0.42–0.88)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>162/224</td>
<td>0.61 (0.45–0.83)</td>
</tr>
<tr>
<td>Other</td>
<td>66/87</td>
<td>0.64 (0.46–0.89)</td>
</tr>
<tr>
<td>Disease status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metastatic</td>
<td>66/90</td>
<td>0.71 (0.43–1.16)</td>
</tr>
<tr>
<td>Persistent/recurrent</td>
<td>238/320</td>
<td>0.59 (0.46–0.76)</td>
</tr>
<tr>
<td>Chemotherapy backbone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboplatin</td>
<td>118/167</td>
<td>0.58 (0.40–0.84)</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>186/243</td>
<td>0.66 (0.49–0.88)</td>
</tr>
<tr>
<td>Prior chemoradiotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>197/263</td>
<td>0.55 (0.42–0.73)</td>
</tr>
<tr>
<td>No</td>
<td>107/147</td>
<td>0.77 (0.52–1.12)</td>
</tr>
<tr>
<td>Histology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>73/89</td>
<td>0.59 (0.45–0.76)</td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>231/321</td>
<td>0.75 (0.47–1.19)</td>
</tr>
</tbody>
</table>

## OS

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>No. events/patients</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>234/410</td>
<td>0.68 (0.52–0.88)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>187/339</td>
<td>0.72 (0.54–0.96)</td>
</tr>
<tr>
<td>≥65</td>
<td>47/71</td>
<td>0.55 (0.31–0.99)</td>
</tr>
<tr>
<td>GOG/ECOG PS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>139/266</td>
<td>0.73 (0.52–1.02)</td>
</tr>
<tr>
<td>1</td>
<td>93/141</td>
<td>0.63 (0.42–0.95)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>128/224</td>
<td>0.72 (0.51–1.02)</td>
</tr>
<tr>
<td>Other</td>
<td>47/87</td>
<td>0.65 (0.45–0.96)</td>
</tr>
<tr>
<td>Disease status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metastatic</td>
<td>50/90</td>
<td>0.85 (0.49–1.49)</td>
</tr>
<tr>
<td>Persistent/recurrent</td>
<td>184/320</td>
<td>0.65 (0.49–0.87)</td>
</tr>
<tr>
<td>Chemotherapy backbone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboplatin</td>
<td>91/167</td>
<td>0.57 (0.38–0.87)</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>143/243</td>
<td>0.78 (0.56–1.08)</td>
</tr>
<tr>
<td>Prior chemoradiotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>156/263</td>
<td>0.61 (0.45–0.84)</td>
</tr>
<tr>
<td>No</td>
<td>78/147</td>
<td>0.86 (0.55–1.34)</td>
</tr>
<tr>
<td>Histology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>55/89</td>
<td>0.62 (0.36–1.06)</td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>179/321</td>
<td>0.72 (0.54–0.97)</td>
</tr>
</tbody>
</table>

Data cut-off: 17 Jul 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months)

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Secondary endpoints: ORR and DoR

**ORR: 84%** (95% CI: 79–89%)

- **CR: 32%**
- **PR: 52%**

**ORR: 72%** (95% CI: 66–78%)

- **CR: 20%**
- **PR: 52%**

---

**DoR Probability**

- **Atezo + bev + CT (n=173)**
  - Events, n (%): 109 (63)
  - Hazard ratio (95% CI): 0.60 (0.46–0.78)
  - Median, months (95% CI): 13.6 (10.6–21.3)

- **Bev + CT (n=147)**
  - Events, n (%): 120 (82)
  - Hazard ratio (95% CI): 0.60 (0.46–0.78)
  - Median, months (95% CI): 8.6 (8.0–10.6)

*Data cut-off: 17 Jul 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months)*

PR = partial response

---

Ana Oaknin, MD, PhD
Summary of efficacy

Consistent results across primary and secondary efficacy endpoints

- **PFS**: Atezo + CT + bev (n=206) 13.7 vs CT + bev (n=204) 10.4
- **TFST**: Atezo + CT + bev (n=206) 19.0 vs CT + bev (n=204) 13.2
- **PFS2**: Atezo + CT + bev (n=206) 25.8 vs CT + bev (n=204) 20.3
- **OS**: Atezo + CT + bev (n=206) 32.1 vs CT + bev (n=204) 22.8

**HR**

- PFS: HR 0.60 (95% CI 0.47–0.76, p<0.0001)
- TFST: HR 0.62 (95% CI 0.49–0.78, p<0.0001)
- PFS2: HR 0.61 (95% CI 0.48–0.79, p=0.0046)
- OS: HR 0.68 (95% CI 0.52–0.88, p=0.0046)

Data cut-off: 17 Jul 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months)
### Summary of safety

<table>
<thead>
<tr>
<th>AE, n (%)</th>
<th>Atezo + bev + CT (n=205)</th>
<th>Bev + CT (n=199)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>202 (99)</td>
<td>197 (99)</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>161 (79)</td>
<td>149 (75)</td>
</tr>
<tr>
<td>Grade 5</td>
<td>7 (3)a</td>
<td>6 (3)b</td>
</tr>
<tr>
<td>AESI for bevacizumab</td>
<td>105 (51)</td>
<td>100 (50)</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>42 (20)</td>
<td>40 (20)</td>
</tr>
<tr>
<td>AESI for atezolizumab</td>
<td>43 (21)</td>
<td>NA</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>11 (5)</td>
<td>NA</td>
</tr>
<tr>
<td>AE leading to any treatment discontinuation</td>
<td>31 (15)</td>
<td>31 (16)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboplatin</td>
<td>4 (2)</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>12 (6)</td>
<td>10 (5)</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>14 (7)</td>
<td>14 (7)</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>18 (9)</td>
<td>19 (10)</td>
</tr>
<tr>
<td>Atezolizumab</td>
<td>13 (6)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*One case each of vaginal haemorrhage, obstructive jaundice and ileal perforation (all considered treatment-related); one case each of intestinal occlusion, biliary bronchoaspiration, nausea/vomiting and septic shock (considered unrelated to treatment). One case each of respiratory failure, intestinal perforation, cardiopulmonary arrest, respiratory infection, COVID infection and intestinal occlusion (considered unrelated to treatment) AE = adverse event; AESI = adverse event of special interest*
All-cause AEs in ≥20% of patients in either arm

Ana Oaknin, MD, PhD
BEATcc confirms the clinical benefit of combining immunosuppression inhibition with angiogenesis inhibition in R/M CC

Adding atezolizumab (anti-PD-L1) to bevacizumab (anti-VEGF) plus chemotherapy provides statistically significant and clinically meaningful improvements in PFS and OS in patients with R/M CC:

- Median PFS: 13.7 vs 10.4 months; HR: 0.62, p<0.0001
- Median OS: 32.1 vs 22.8 months; HR: 0.68, p=0.0046

Meaningful improvements seen in all key secondary endpoints

- Higher ORR and longer DoR
- Longer TFST and PFS2

Predictable and manageable safety profile and no new safety signals with atezolizumab in combination with bevacizumab plus platinum-based chemotherapy

Atezolizumab in combination with bevacizumab added to platinum-based chemotherapy should be considered a new first-line therapy option for patients with metastatic, persistent or recurrent cervical cancer
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W Mina
B Billemont

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K Lindemann
L Bjørge
A Gry Bentzen
K Hellman
H Dahlstrand
O Derke
M Bjurberg
A Koliadi

**GEICO**
A Oaknin
M Jesús Rubio
A Redondo
P Barretina
E Guerra
L Manso
J Martínez
J Alarcón
J Fernando Cueva
A Pérez-Fidalgo
B Pardo
L Gaba
Y García
N Anzizar
A Herrera
A Godoy Ortiz

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GINECO (France)
S Abadie Lacourtoisie
L Mansi
A Floquet
C Lebreton
F Joly
I Ray-Coquard
M Fabbro
V D’Hont
A Lorholary
P Follana
F Selle
A Angelergues
N Delanoy
B You
A-C Hardy-Bessard
D Berton

**MITO** (Italy)
U De Giorgi
C Casanova
A Frassoldati
A Bologna
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D Lorusso
G Valabrega
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C Pisano
C Andreotta
G Ronzino

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D Katsaros

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T Fehm

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