Conclusions

- Dostarlimab demonstrated durable antitumor activity in both dMMR and MMRp advanced/recurrent EC. The dMMR status as detected by IHC was associated with a higher response rate.

- The primary endpoints were ORR and DOR by RECIST v1.1 by blinded independent central review (BICR).

- The standard for quantifying antitumor activity, RECIST v1.1, has some deficits as it pertains to measuring the antitumor activity of immunotherapies.

Results (cont’d)

- 126 patients with dMMR EC and 145 patients with MMRp EC had been enrolled and treated as of the data cutoff date of March 1, 2020. Two patients were removed from safety populations of cohorts A1 and A2, respectively (Figure 2).

- The efficacy endpoints reported by RECIST v1.1 and irRECIST were consistent.

- Dostarlimab is being evaluated in first-line EC in the RUBY clinical trial (NCT03897186) in combination with standard-of-care chemotherapy.

Background

- Endometrial cancer (EC) is the most common gynecologic malignancy in the US and European Union.

- EC has demonstrated the highest rates of mismatch repair-deficient (dMMR) and microsatellite instability-high (MSI-H) tumors among all tumors (approximately 30%).

- Treatment options are limited for patients with disease progression that occurs on or after first-line therapy, and overall survival is typically < 1 year.

- Pembrolizumab has been approved in the US for patients with unresectable or metastatic MSI-H or dMMR sold tumors, including EC, who have progressing prior treatment and have no satisfactory alternative treatment option.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Dostarlimab (TSR-042) is an investigational, humanized, anti-programmed cell death (anti-PD-1) monoclonal antibody that competitively inhibits the PD-1 receptor and blocks ligand binding (PD-L1 and PD-L2).

- Pembrolizumab + lenvatinib has been approved in the US, Canada, and Australia for patients with unresectable or metastatic MSI-H or dMMR EC and EC with documented progression during or within 6 months of prior checkpoint inhibitor therapy.

- Treatment options are limited for patients with disease progression.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US, Canada, and Australia for patients with unresectable or metastatic MSI-H or dMMR EC and EC with documented progression during or within 6 months of prior checkpoint inhibitor therapy.

- Treatment options are limited for patients with disease progression.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.

- Pembrolizumab + bevacizumab has been approved in the US, Canada, and Australia for patients with advanced EC that is not MSI-H or dMMR and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

- Pembrolizumab + lenvatinib has been approved in the US for patients with MMRp EC.