Real-world data on dostarlimab in post-platinum mismatch repair deficient (dMMR)/microsatellite instability high (MSI-H) advanced/recurrent (A/R) endometrial cancer: descriptive analysis of the French cohort Temporary Authorization of Use (cATU)

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Background

In February 2020, the French National Health Agency (Agence nationale de sécurité du médicament et des produits de santé) (ANSM) provided a Temporary Authorization of Use (among patients with dMMR/MSI-H advanced/recurrent endometrial cancer (ER) with no other available treatment options) for dostarlimab (50 mg/mL 50 mL vials) for the treatment of ER (tm) according to the European Union Medical Device Regulation (EU 2017/745).

Methods

Patients with advanced/recurrent endometrial cancer treated with dostarlimab in the cATU were included in the cohort expanded access scheme (N=59). The cATU was authorized in October 2020 for patients with dMMR/MSI-H ER who had no alternative treatment options and met the eligibility criteria.

Results

None of the patients in the 4-month period showed disease progression. Median (SD) weight was 87 (±9.2) kg, and median (SD) number of cycles was 6 (±2.9). Two of the 15 patients (13%) with similar characteristics had a partial response, 5 (41.7%) had stable disease, and 8 (66.7%) had progressive disease. No patients achieved complete response.

Conclusions

The cATU was authorized in France in October 2020 for patients with advanced/recurrent endometrial cancer. The treatment efficacy and safety were consistent with the results observed in clinical trials.

Table 1. Baseline characteristics of patients treated with dostarlimab in the cohort expanded access scheme (N=59).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
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<tr>
<td>Age at start of dostarlimab (years)</td>
<td>60 (98)</td>
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<tr>
<td>Performance status, n (%)</td>
<td>0 (0)</td>
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<tr>
<td>Weight (kg), med (range)</td>
<td>87 (77-105)</td>
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</tbody>
</table>
| Baseline characteristics of the 80 patients considered to have received dostarlimab treatment in the cATU are shown in Table 1.

Acknowledgments

The authors declare no conflicts of interest.

References

3. Clovis and Novartis.
4. GSK, Lilly, Novartis, and Pfizer.
5. NCT02715284.
6. GARNET trial.