Background

Objective

Methods

Conclusions

Results

Table 1. Safety Summary

Table 2. Patients on Treatment at the Start of Each DoseRegimen Cycle

Table 3. Resolution of Grade ≥3 TRAEs

References

Dostarlimab is a humanized engineered death-1 (PD-1) receptor monoclonal antibody that blocks interaction with the ligands PD-L1 and PD-L2.

In the US, dostarlimab is approved as a monotherapy in adult patients with recurrent or advanced dMMR/microsatellite-ineligible, high-grade solid tumors that have progressed on or after a platinum-containing regimen1-3:

- A dMMR solid tumor that has progressed on or after prior treatment and who have no satisfactory alternative treatment options available.

In the EU, dostarlimab is approved as a monotherapy in adult patients with recurrent or advanced dMMR/microsatellite-ineligible, high-grade solid tumors that have progressed on or after treatment with a platinum-containing regimen1-3:

GARNET (NCT02715284) is a phase 1 study assessing the antitumor activity and safety of dostarlimab monotherapy in patients with solid tumors1-3.

No new safety signals were detected with dostarlimab compared to other anti-PD-1 blockers.

Most treatment-related adverse events (TRAEs) were low grade and occurred in the first 4 cycles (the first 12 weeks of treatment): Some cases occurred later, suggesting a need for ongoing monitoring.

The TRAE hypothyroidism peaked during cycle 4 and occurred throughout the study period.

Few increases in the incidence of TRAEs were seen during cycles 5. Following the transition to the 1000 mg every 6 weeks (Q6W) dosing schedule:

• The TRAEs with increased incidence after transition were fatigue and hypothyroidism.

Across the categories of grade ≥3 TRAEs observed, the majority received with a median time to resolution ranging from 1 to 30 days.

TRAEs occurring in ≥10% of patients, by cycle

Figure 2. TRAEs Occurring in ≥10% of Patients, by Cycle

Figure 3. Grade 3 TRAEs Occurring in ≥1% of Patients, by Cycle

Figure 4. Most Common ≥3 TRAE: Hypothyroidism, by Cycle

TRAEs occurring in ≥1% of patients.

Table 3. Most Common ≥3 TRAEs, by Cycle

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