Background

Dostarlimab is a humanized programmed death 1 (PD-1) receptor monoclonal antibody that blocks interaction with the ligands PD-L1 and PD-L2. In the EU, dostarlimab is approved as a monotherapy in adult patients with recurrent or advanced mismatch repair deficient (dMMR) endometrial cancer (EC) that has progressed on or after treatment with a platinum-containing regimen.

In the US, dostarlimab is approved as a monotherapy in adult patients with the following: - dMMR recurrent or advanced EC that has progressed on or after a platinum-containing regimen; - a dMMR solid tumor that has progressed on or after prior treatment and who have no satisfactory alternative treatment options.

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

Methods

This multicenter, open-label, single-arm study is being conducted in 2 parts: dose escalation and expansion (Figure 1). In part 2B, dostarlimab was administered at the recommended therapeutic dose determined from parts 1 and 2A (Figure 2).

Results

Objective

To report on TRAEs and immune-related TRAEs (irTRAEs) across the 2B expansion cohorts of the GARNET trial

Conclusions

Safety with dostarlimab was consistent with the anti-PD-1 drug class.

Safety was consistent across tumor types.

Most treatment-related adverse events (TRAEs) were low grade, with few leading to interruption or discontinuation.

No overall increase in the rate of TRAEs was seen after transitioning to the 1000 mg Q6W dosing schedule.

Safety outcomes were consistent across tumor types.

TRAEs and irTRAEs leading to interruption or discontinuation were low, at 3% and 4%, respectively.

The majority of TRAEs and irTRAEs were low grade (53.7% and 53.6%, respectively) and grade 3 or 4.

TRAEs were spread across all systems.

No spike in the rate of TRAEs or irTRAEs was seen at dose change from 500 mg IV Q3W to 1000 mg IV Q6W.