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Clinical complete response with dostarlimab monotherapy in dMMR/MSI-H locally advanced rectal cancer (LARC): First results from the global registrational AZUR-1 trial

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Background

Multimodal treatment with chemotherapy, radiation and surgery is a standard of care (SOC) for LARC associated with significant toxicity/morbidity. After TNT, the range of clinical complete response (cCR) is 21–41%. dMMR/MSI-H tumours are exceptionally responsive to PD-1 blockade: in a small study, neoadjuvant dostarlimab treatment led to durable cCRs and eliminated the need for SOC in most patients (pts) with LARC. AZUR-1 (NCT05723562) is a global single-arm trial and the first registrational study evaluating the clinical benefit of dostarlimab monotherapy in pts with dMMR/MSI-H LARC.

Methods

Dostarlimab 500 mg was administered IV every 3 weeks for 9 cycles. Key endpoints include rate of sustained cCR for 12 months (cCR12) following end of treatment (EOT) with dostarlimab alone by investigator (INV) and independent central review (ICR), and composite rate of cCR12 (INV) + pathological CR (pCR).

Results

At data cutoff (DCO, 20 April 2026), 154 pts were enrolled and median follow-up was 26.3 months (range 2–36). Of 144 pts with ≥12 months follow-up, 68% achieved cCR12 (INV). Of 15 pts who underwent surgery after dostarlimab alone, 12 (80%) had pCR, resulting in a cCR12+pCR rate of 76%. Fewer pts were cCR12-evaluable by ICR, primarily due to cCR being confirmed later by ICR after initial EOT evaluation. Of pts evaluable by ICR, 47% (54/116) achieved cCR12, with 38 pts in cCR and being followed for cCR12 at DCO. 98% of pts who achieved cCR remained in cCR for ≥12 months by INV or ICR, with no recurrences to date for pts who achieved cCR or pCR. Overall, 93% of patients are in surveillance with no evidence of disease progression after treatment (dostarlimab ± SOC) and 71% achieved this outcome with dostarlimab alone. The safety profile was acceptable: 88% of pts completed all 9 cycles of dostarlimab and Grade ≥3 immune-mediated AEs occurred in 4 pts.

Conclusions

In this AZUR-1 interim analysis, 68% of pts achieved cCR12 and 76% achieved cCR12+pCR with dostarlimab alone with no disease recurrences to date. These durable responses indicate the potential to eliminate the need for chemotherapy, radiation and surgery, and

redefine the curative-intent treatment paradigm for pts with dMMR/MSI-H LARC.

Clinical trial identification

NCT05723562.

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Legal entity responsible for the study

GSK.

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Disclosure

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