

A complete listing of sites and additional information for this clinical trial can be found at clinicaltrials.gov/study/NCT06948448.



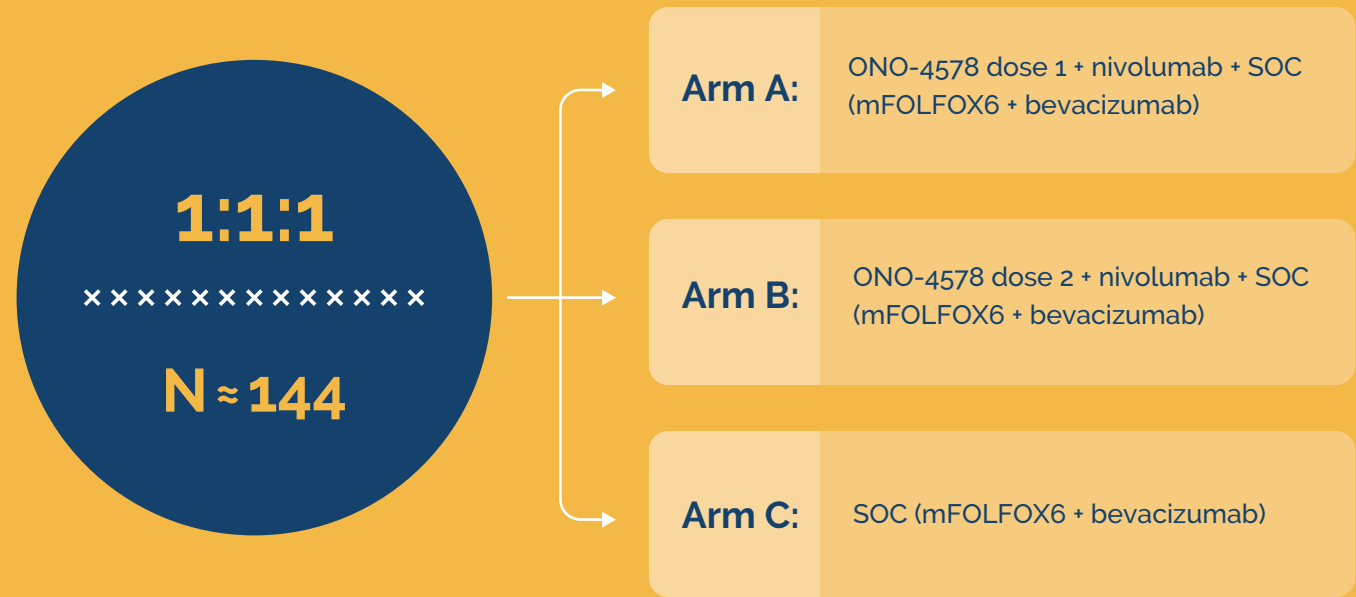
For more information, email medicalinformation@deciphera.com

} ONO-4578

A Phase 2, Randomized, Open Label, Multicenter Study to Evaluate the Safety and Efficacy of Two Dose Levels of ONO-4578 With Opdivo[®] in Combination With mFOLFOX6 and Bevacizumab Versus Standard of Care for First-line Treatment of Non-MSI-H/dMMR, PD-L1 Positive Advanced Colorectal Cancer

Study Design

A Phase 2, randomized, open label, multicenter study to evaluate the safety and efficacy of two dose levels of ONO-4578 with Opdivo® when added to mFOLFOX6 + bevacizumab versus SOC as first-line treatment for advanced CRC



Primary Outcome Measures

- Overall Response Rate (ORR) per Blinded Independent Central Review (BICR)
- Number of participants with Adverse Events (AEs)
- Number of participants with Serious Adverse Events (SAEs)

Secondary Outcome Measures

- Overall Survival (OS)
- Progression-Free Survival (PFS)
- Best overall response (BOR)
- Duration of response (DOR)
- Disease Control Rate (DCR)
- Time to Response (TTR)

Select Inclusion Criteria

- 18 Years and older
- Histologically confirmed advanced (locally advanced or metastatic) colorectal cancer not amenable to curative resection
- ECOG Performance Status of 0-1
- No prior systemic treatment for advanced local or mCRC
- Participants whose tumor is positive for PD-L1 expression as determined at a central laboratory

Select Exclusion Criteria

- Participants with high microsatellite instability (MSI-High), or mismatch repair deficient (dMMR) tumor
- Participants with BRAF V600E mutation
- Unable to swallow tablets
- Participants with complication or history of interstitial lung disease, pneumonitis or pulmonary fibrosis
- Participants with an active, known or suspected autoimmune disease
- Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways

Abbreviations: CRC=colorectal cancer; ECOG=Eastern Cooperative Oncology Group; mCRC=metastatic colorectal cancer; SOC=standard of care

ONO-4578 (a highly selective, oral EP4 receptor antagonist that inhibits PGE2 signaling) is an investigational drug that has not been approved by the US FDA, European Commission, or any other regulatory agency.