

A complete listing of sites and additional information for this clinical trial can be found at clinicaltrials.gov/study/NCT06630234.



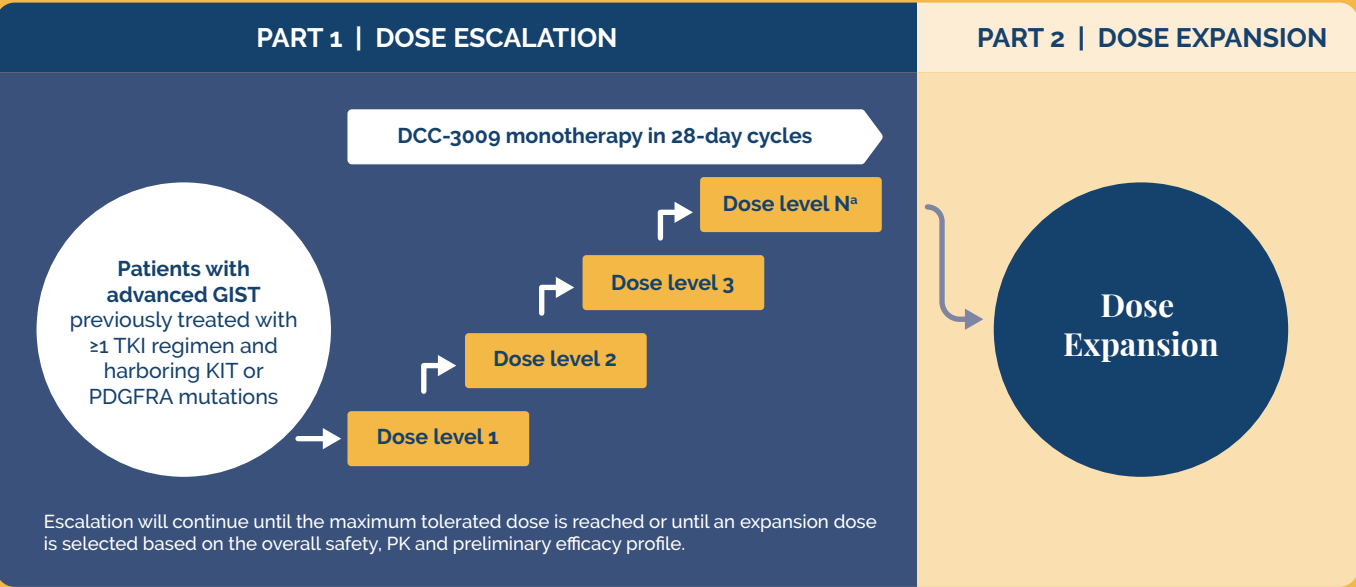
For more information, email
medicalinformation@deciphera.com

} DCC-3009

A Phase 1/2 Open-Label Study of
DCC-3009* in Patients with Advanced
Gastrointestinal Stromal Tumor

Study Design

Phase 1/2, multi-cohort, open-label trial evaluating the safety, tolerability, and efficacy of DCC-3009 in patients with advanced GIST



Primary Outcome Measures

Part 1: Dose Escalation Phase

- Dose-limiting toxicities will be assessed for each dose level
- Safety assessments will include monitoring of treatment-emergent adverse events and serious adverse events

Secondary Outcome Measures

- Objective response rate (ORR)
- Duration of response (DOR)
- Progression-free survival (PFS) per mRECIST v1.1
- Overall survival (OS)
- Pharmacokinetic (PK) analysis

Select Inclusion Criteria

Part 1: Dose Escalation Phase

- Patients ≥18 years of age
- Any participant with histologically or cytologically confirmed advanced/ unresectable or metastatic GIST with documented KIT or PDGFRA mutation, who has progressed on, or was intolerant of, at least 1 approved TKI regimen in the advanced/metastatic setting
- Have at least 1 measurable lesion as defined by mRECIST v1.1
- Have an ECOG Performance Status of 0 or 1
- Adequate organ function, bone marrow function, and electrolytes
- All participants agree to comply with the contraception requirements
- Have a life expectancy of more than 3 months

Select Exclusion Criteria

- Received systemic anticancer therapy or radiotherapy within 14 days prior to first dose of study drug
- Prior or concurrent malignancy that requires treatment or is expected to require treatment for active cancer
- Has known active CNS metastases or an active primary CNS cancer
- History or presence of clinically relevant cardiovascular abnormalities
- Major surgery within 28 days of the first dose of study drug
- Had systemic arterial thrombotic or embolic events within 6 months prior to the first dose of study drug
- Had venous thrombotic events (e.g., deep vein thrombosis) or venous thrombotic embolic events (e.g., pulmonary embolism) within 1 month prior to the first dose of study drug
- Known allergy or hypersensitivity to any component of the study drug
- Malabsorption syndrome or other illness that could affect oral absorption

Abbreviations: CNS=central nervous system; ECOG=Eastern Cooperative Oncology Group; GIST=Gastrointestinal Stromal Tumor; mRECIST v1.1=Modified Response Evaluation Criteria in Solid Tumors version 1.1; PDGFRA=platelet-derived growth factor receptor alpha; TKI=tyrosine kinase inhibitor

DCC-3009 (a switch-control KIT and PDGFRA inhibitor) is an investigational drug that has not been approved by the US FDA, European Commission, or any other regulatory agency.