



A Study of DCC-2618* vs Sunitinib in Advanced GIST Patients After Treatment with Imatinib (intrigue)



A Phase 3, Interventional, Randomized, Multicenter, Open-Label Study of DCC-2618 vs Sunitinib in Patients with Advanced Gastrointestinal Stromal Tumors after Treatment with Imatinib (intrigue)

Study Design

- This is a 2-arm, randomized, open-label, international, multicenter study comparing the efficacy of DCC-2618 to sunitinib in GIST patients who progressed on or were intolerant to first-line anticancer treatment with imatinib.
- Approximately 358 patients will be randomized in a 1:1 ratio to DCC-2618 150 mg once daily (QD) or sunitinib 50 mg QD, 4 weeks on, 2 weeks off.

Primary Outcome Measures

- Progression free survival (PFS) based on independent radiologic review using modified RECIST.

Secondary Outcome Measures

- Objective response rate (ORR) as determined by confirmed CR + confirmed PR by independent radiologic review.
- Measure of Overall Survival (OS).
- To compare the safety profile of DCC-2618 to the safety profile of sunitinib.

Select Inclusion Criteria

- Patients ≥ 18 years of age at the time of informed consent.
- Histologic diagnosis of GIST and must be able to provide an archival tumor tissue sample, otherwise, a fresh biopsy is required.
- Patients must have progressed on imatinib or have documented intolerance to imatinib.
- Eastern Cooperative Oncology Group (ECOG) PS of ≤ 2 at screening.
- Adequate organ function and bone marrow reserve as indicated by the central laboratory assessments performed at screening.
- Resolution of all toxicities from prior therapy to \leq Grade 1 (or patient baseline) within 1 week prior to the first dose of study drug (excluding alopecia and \leq Grade 3 clinically asymptomatic lipase, amylase, and creatine phosphokinase [CPK] laboratory abnormalities).
- The patient is capable of understanding and complying with the protocol and has signed the informed consent document. Signed informed consent form (ICF) must be obtained before any study-specific procedures are performed.
- Molecular pathology report must be available. If molecular pathology report is not available or insufficient, an archival tumor tissue sample or fresh biopsy is required for mutation status confirmation by the central laboratory prior to randomization.
- Patients must have at least 1 measurable lesion according to mRECIST Version 1.1 (non nodal lesions must be ≥ 1.0 cm in the long axis or \geq double the slide thickness in the long axis) within 21 days prior to the first dose of study drug.

Select Exclusion Criteria

- Treatment with any other anti-cancer therapy in addition to imatinib for advanced GIST.
- Patients with a prior or concurrent malignancy whose natural history or treatment have the potential to interfere with the safety or efficacy assessment of this clinical trial are not eligible.
- Patient has known active central nervous system metastases.
- New York Heart Association class II-IV heart disease, myocardial infarction within 6 months of cycle 1 day 1, active ischemia or any other uncontrolled cardiac condition such as angina pectoris, clinically significant cardiac arrhythmia requiring therapy, uncontrolled hypertension or congestive heart failure.
- Major surgeries (e.g. abdominal laparotomy) within 4 weeks of the first dose of study drug. All major surgical wounds must be healed and free of infection or dehiscence before the first dose of study drug.
- Any other clinically significant comorbidities.
- Known human immunodeficiency virus or hepatitis C infection only if the patient is taking medications that are excluded per protocol, active hepatitis B, or active hepatitis C infection.
- Known allergy or hypersensitivity to any component of the study drug.
- Gastrointestinal abnormalities including but not limited to:
 - inability to take oral medication
 - malabsorption syndromes
 - requirement for intravenous (IV) alimentation
- Any active bleeding excluding hemorrhoidal or gum bleeding.

The network of sites for clinical trial DCC-2618-03-002 is being updated.
A complete listing of current sites for this clinical trial can be found on www.clinicaltrials.gov.

For more information:

Please contact clinicaltrials@deciphera.com or visit clinicaltrials.gov

*DCC-2618 is an investigational drug that has not been approved by the FDA.