CLINICAL STUDY
Protocol DCC-2618-01-001

A Multicenter Phase 1, Open-Label Study of DCC-2618 to Assess Safety, Tolerability, Efficacy, and Pharmacokinetics in Patients with Advanced Malignancies

Study Design

Escalation Phase: Evaluating safety at increasing doses of single-agent DCC-2618 administered in repeated 28-day cycles in patients with advanced malignancies with a molecular rationale for activity.

Expansion Phase: Testing for further safety, PK, PD, and evidence of antitumor activity across a variety of tumors with evidence of alterations in genes that are targets of DCC-2618 as follows:

- KIT or PDGFRA Mutant Gastrointestinal Stromal Tumors [GIST]
- Systemic Mastocytosis (SM) and other Hematologic Malignancies
- Malignant Gliomas
- Other Solid Tumors

Status

Escalation Phase: Closed to enrollment
Expansion Phase: Open to enrollment in US and Canada, EU sites opening in early 2018

Key Eligibility criteria for GIST Patients

- ✓ Must have a KIT or PDGFRA mutation and must have progressed on or had an intolerability to at least 1 but not more than 4 lines of systemic anticancer therapy:
  - Patients must have progressed on imatinib for tumors with known imatinib-sensitive mutations or be intolerant or have a known contraindication to imatinib.
  - Patients with a pre-existing resistance mutation to an approved line of therapy are eligible. For example, imatinib resistant mutations including KIT Exon 17 and PDGFRA D842V.
- ✓ Patients with known CNS metastases may participate (with provisions)
- ✓ Patients must have an archival tumor biopsy sample as long as no anticancer therapy was administered since the sample was collected; otherwise, a current biopsy is required.
- ✓ Male or female patients ≥18 years of age.
- ✓ Eastern Cooperative Oncology Group (ECOG) performance status (PS) of ≤2.
- ✓ Patients must have at least 1 measurable lesion according to RECIST Version 1.1
- ✓ Adequate organ function and bone marrow function