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

This study will be conducted according to the protocol and in compliance with Good Clinical Practice, the ethical principles stated in the Declaration of Helsinki, and other applicable regulatory requirements.