deciphera

A Phase 1 Study of DCC-2618: Systemic Mastocytosis Expansion Cohort*

Part 1: DCC-2618 Dose Escalation

Enrollment complete

Patients with Advanced Cancers (including Aggressive Systemic Mastocytosis)

Part 2: DCC-2618 Expansion Cohort:

Currently enrolling

Patients with Systemic Mastocytosis and other hematologic malignancies.

Study Design

DCC-2618-01-001 is a phase 1, open-label study designed to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and preliminary antitumor activity of **DCC-2618**, administered orally (PO), in adult patients with advanced malignancies, including Systemic Mastocytosis (SM) and other hematologic malignancies. The study consists of 2 parts, a dose-escalation phase and an expansion phase.

Select Inclusion Criteria:

- Aged 18 years or older
- Eastern Cooperative Oncology Group (ECOG) performance status (PS) of ≤2.
- Histologically confirmed malignancies with the following criteria:
  - SM patients must have a confirmed diagnosis (by a central independent pathologist) of advanced SM according to 2016 WHO criteria and documented KIT mutant disease. SM patients must also have a normal karyotype.
  - Advanced SM includes: ASM, SM-AHN, wherein the AHN does not require immediate alternative therapy, such as acute myeloid leukemia. AHNs that are eligible include: low grade myelodysplastic syndrome (MDS) with a high SM burden who require treatment for SM only, myeloproliferative neoplasms (MPNs), MDS/MPN, and HES/CEL], and MCL. Patients with advanced SM must present with at least 1 eligible C-Finding (organ damage).
  - Patients with imatinib-sensitive KIT mutations must have progressed on or were intolerant to a tyrosine kinase inhibitor.
  - Patients with symptomatic SSM are eligible (at least 2 B-findings, and clinically significant symptom despite maximal treatment with approved agents to treat mediator symptoms). Patients must have a normal karyotype.
  - Patients with hematologic malignancies featuring clonal expansion of eosinophils driven by genomic alterations of KIT or PDGFR (eg, HES or CEL) must have a diagnosis confirmed by a central independent pathologist and are eligible if they have progressed on or are intolerant of imatinib therapy. Patients with de novo imatinib resistant mutations, such as but not limited to KIT D816V or PDGFRA D842V, are eligible without prior imatinib therapy.

Endpoints:

- Safety
- Tolerability
- PK
- Maximum tolerated dose
- Recommended Phase 2 dose
- Anti-tumor activity

For more information:

Please contact
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or visit clinicaltrials.gov

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