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A complete listing of sites and additional information for this clinical trial can be found at **clinicaltrials.gov/study/NCT05957367**.

For more information, email
**medicalinformation@deciphera.com**

# Inlexisertib+Ripretinib

## **A Phase 1/2,** Open-Label Study of Inlexisertib (DCC-3116)* in Combination with Ripretinib in Participants with Advanced Gastrointestinal Stromal Tumor

*Inlexisertib (a switch control kinase inhibitor of Unc-51-like autophagy- activating kinase [ULK] 1/2) is an investigational drug that has not been approved by the US FDA, European Commission, or any other regulatory agency.

Ripretinib is indicated for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib. The recommended dose of ripretinib is 150 mg (three 50 mg tablets) taken once daily at the same time with or without food.

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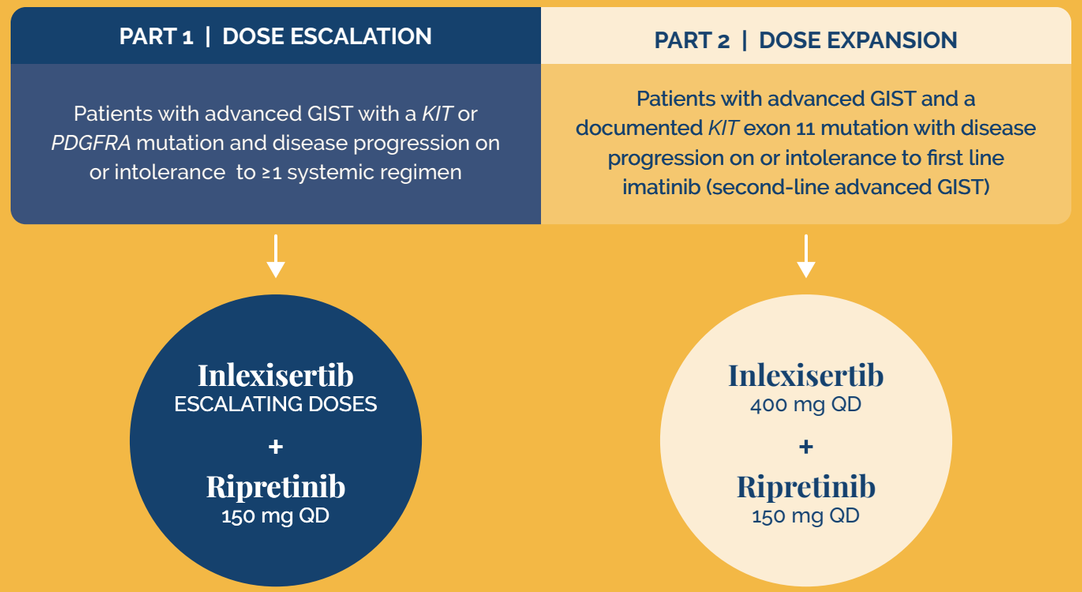
DCPH-M01165v1 05/26

# Study Design

Phase 1/2, multicenter, open-label study of inlexisertib in combination with ripretinib




## Primary Outcome Measure

**Part 2: Dose Expansion Phase**

- Objective response rate (ORR) per mRECIST v1.1

## Secondary Outcome Measures

**Part 2: Dose Expansion Phase**

- Progression free survival (PFS)
- Duration of response (DOR)
- Overall Survival (OS)
- Pharmacokinetic (PK) analysis

## Select Inclusion Criteria

**Part 2: Dose Expansion Phase**

- Pathologically confirmed GIST with documented mutation in KIT exon 11
- Progression or intolerance on imatinib given in the locally advanced or metastatic setting and may not have received additional systemic therapy for GIST
- Male or female ≥18 years of age
- At least 1 measurable lesion according to mRECIST v1.1
- Must have a life expectancy of more than 3 months and an ECOG performance status of 0-1
- Adequate organ function and bone marrow reserve

## Select Exclusion Criteria

**Part 2: Dose Expansion**

- Received anticancer therapies or investigational therapies within 14 days or 5x the half-life (whichever is shorter)
- Received anticancer therapies or medications including certain herbal medications that are known strong or moderate inhibitors or inducers of CYP3A4 or P-glycoprotein within ≤14 days or 5x the half-life (whichever is longer)
- History or presence of clinically relevant cardiovascular abnormalities ≤6 months prior to the first dose of study drug
- Ongoing participation in an interventional study
- Active viral infection (including HIV, hepatitis B, or hepatitis C)
- Known allergy to ripretinib or inlexisertib and their excipients
- Known active metastasis of the central nervous system or presence of leptomeningeal disease
- Previous treatment with systemic therapy for GIST other than imatinib

Abbreviations: ECOG=Eastern Cooperative Oncology Group; GIST=Gastrointestinal Stromal Tumor; mRECIST=modified Response Evaluation Criteria in Solid Tumors version 1.1; QD=once daily

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