# S1304: Expanded Lab Data Collection

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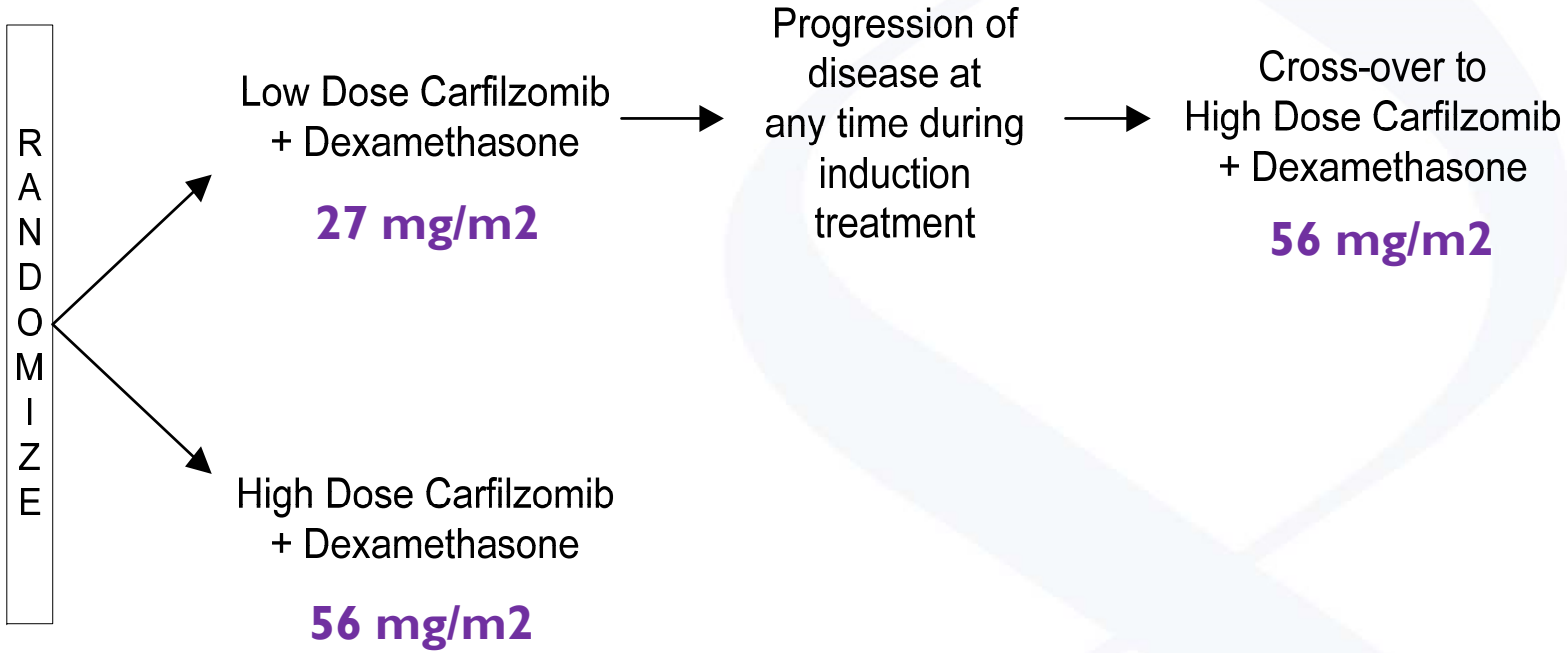
# S1304 Overview

**A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease**



# Why collect additional data?

- Short term objective: gather data needed to provide FDA with additional safety and efficacy information on the studied dose levels of carfilzomib.
- Our ultimate objective: improve dosing for future patients.

# What data will be collected?

- Post-baseline labs:
  - Hematologic: ANC, Platelets, Hgb
  - Hepatic: AST, ALT, total bilirubin
  - Renal: creatinine, measured creatinine clearance, calculated creatinine clearance

# At what interval?

- Every cycle for first 12 cycles, then every year until progression, at time of progression, and at regular follow-up visits.

# Scope

- Protocol to be amended
- New eCRF to be created
- Data to be retrospectively submitted for all patients with follow-up
- Extra funds will be made available
- Memo explaining details will be provided
- No clinical monitor visits!

# Questions?