# Study to Evaluate the Safety and Tolerability of CC-92328 in Participants With Relapsed and/or Refractory Multiple Myeloma

| CLINICALTRIALS.GOV IDENTIFIER | RECRUITMENT STATUS | FIRST POSTED | LAST UPDATE POSTED |
|---|---|---|---|
| NCT04975399 | RECRUITING | JULY 23, 2021 | FEBRUARY 7, 2022 |

## STUDY DESCRIPTION

### Brief Summary

This Phase 1, first-in-human (FIH), clinical study of CC-92328 will explore the safety, tolerability and preliminary biological and clinical activity of CC-92328 as a single-agent in the setting of relapsed and/or refractory multiple myeloma (R/R MM). The study will be conducted in two parts: monotherapy dose escalation (Part A) and monotherapy dose expansion (Part B).

**Condition or Disease:** Multiple Myeloma

**Intervention/treatment:** Drug: CC-92328

**Phase:** Phase 1

## DETAILED DESCRIPTION

N/A

## STUDY DESIGN

**Study Type:** Interventional

**Estimated Enrollment :** 70 participants

**Intervention Model :** Single Group Assignment

**Masking:** None (Open Label) ()

**Primary Purpose:** Treatment

**Official Title:** Study to Evaluate the Safety and Tolerability of CC-92328 in Participants With Relapsed and/or Refractory Multiple Myeloma

**Actual Study Start Date:** October 2021

**Estimated Primary Completion Date:** February 2026

**Estimated Study Completion Date:** February 2026

## ARMS AND INTERVENTIONS

| Arm | Intervention/treatment |
|---|---|
| Experimental: Administration of CC-92328<br>CC-92328 administered intravenously in 28-day cycles | Drug: CC-92328<br>CC-92328 |

## OUTCOME MEASURES

Primary Outcome Measures:

1. Dose-Limiting Toxicities (DLTs) [ Time Frame: Up to 28 days after the first dose ]
   Are defined as toxicities that meet the protocol-specified criteria occurring within the DLT assessment window (Cycle 1, Days 1 to 28) except those that are clearly and incontrovertibly due to the underlying disease or extraneous causes.
2. Maximum Tolerated Dose (MTD) [ Time Frame: Up to 9 weeks after the last dose ]
   Defined as the highest dose at which less than 33% of the population treated with CC-92328 experience a dose-limiting toxicity (DLT) in the first cycle and at least 6 evaluable participants have been treated at this dose level.
3. Incidence of Adverse Events (AEs) [ Time Frame: Up to 9 weeks after the last dose ]
   Type, frequency, seriousness, severity and relationship of AEs to CC-92328.

Secondary Outcome Measures:

1. Preliminary Efficacy - Overall Response Rate (ORR) [ Time Frame: Up to approximately 2 years ]
   Defined as the proportion of participants who achieve a partial response (PR) or better according to IMWG response criteria.
2. Preliminary Efficacy - Time to response [ Time Frame: Up to approximately 2 years ]
   Defined as the time from the first CC-92328 dose date to the date of first documented response (PR or better).
3. Preliminary Efficacy - Duration of response [ Time Frame: Up to approximately 2 years ]
   Defined as the time from the earliest date of documented response (≥ PR) to the first documented disease progression or death, whichever occurs first.
4. Preliminary Efficacy - Progression-free Survival (PFS) [ Time Frame: Up to approximately 2 years ]
   Defined as the time from the first dose of CC-92328 to pharmacodynamics (PD) or death from any cause, whichever occurs first.
5. Preliminary Efficacy - Overall Survival (OS) [ Time Frame: Up to approximately 2 years ]
   Defined as the time from the first dose of CC-92328 to death from any cause.
6. Pharmacokinetics - Cmax [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
   Maximum serum concentration of drug.
7. Pharmacokinetics - Cmin [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
   Minimum serum concentration of drug.
8. Pharmacokinetics - AUC [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
   Area under the curve.
9. Pharmacokinetics - tmax [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
   Time to peak (maximum) serum concentration.
10. Pharmacokinetics - t1/2 [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
    Half-life.
11. Pharmacokinetics - CL [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
    Total body clearance of the drug from the serum.

12. Pharmacokinetics - Vd [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
Volume of distribution.
13. Pharmacokinetics - Accumulation index of CC-92328 [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
Calculated from the serum concentration-time data of CC-92328 using non-compartment methods.
14. Presence of Anti-CC92328 antibodies (ADA) [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
Determined using a validated bridging immunoassay with electrochemiluminescence detection.
15. Frequency of Anti-CC92328 antibodies (ADA) [ Time Frame: Day 1 to 9 weeks after last dose of study drug ]
Determined using a validated bridging immunoassay with electrochemiluminescence detection.

---

**ELIGIBILITY CRITERIA**

**Ages Eligible for Study:** 18 Years and older (Adult, Older Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

**Criteria**

Inclusion Criteria:
Participants must satisfy the following criteria to be enrolled in the study:
must understand and voluntarily sign an informed consent form (ICF) prior to any study-related assessments/procedures being conducted. willing and able to adhere to the study visit schedule and other protocol requirements. Participant is ≥ 18 years of age the time of signing the ICF. Participant has a history of multiple myeloma (MM) with relapsed and/or refractory disease who have failed or who are ineligible or intolerant to available therapies that may provide clinical benefit. Have documented disease progression on or within 12 months from the last dose of their last myeloma therapy. Participant must have measurable disease. Participant has an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1. Females of childbearing potential (FCBP) must commit to true abstinence from heterosexual contact or agree to use at least one method of highly effective contraception without interruption from screening to at least 9 weeks after the last dose of CC-92328 Males must practice true abstinence or agree to use a condom FCBP and males must avoid conceiving from signing the ICF, while participating in the study, during dose interruptions, and for at least 9 weeks after the last dose of CC-92328.
Exclusion Criteria:
The presence of any of the following will exclude a participant from enrollment:
Participant has symptomatic central nervous system involvement of MM. Participant had a prior autologous stem cell transplant ≤ 90 days prior to starting CC-92328. Participant had a prior allogeneic stem cell transplant with either standard or reduced intensity conditioning ≤ 12 months prior to starting CC-92328. Participant had prior systemic cancer-directed treatments or investigational modalities ≤ 5 half-lives or 4 weeks prior to starting CC-92328, whichever is shorter. Participant is a pregnant or lactating female. Participant received live virus vaccines within at least 4 weeks prior to starting study drug. Participant has known active human immunodeficiency virus (HIV) infection. Participant has active hepatitis B or C (HBV/HCV) infection. Participant weight is ≤ 40 kg at screening.

---

**CONTACTS AND LOCATIONS**

**Contacts**

Contact: Recruiting sites have contact information. Please contact the sites If there is no contact information, please email: Clinical.Trials@bms.com
Contact: First line of the email MUST contain NCT # and Site #.

**Locations**

| | | |
|---|---|---|
| United States, Alabama | University of Alabama at Birmingham Hospital | Birmingham |
| United States, Arizona | HonorHealth Research Institute | Scottsdale |
| United States, Florida | University of South Florida (USF) | Tampa |
| United States, Maryland | Johns Hopkins Oncology Center | Baltimore |
| United States, New York | Memorial Sloan-Kettering Cancer Center - David H. Koch Center for Cancer Care | New York |
| United States, New York | Mt. Sinai Medical Center Division of Hematology/Oncology | New York |
| United States, Wisconsin | Froedtert Hospital BMT Medical College of Wisconsin | Milwaukee |
| Canada, Alberta | Tom Baker Cancer Center | Calgary |
| Canada, Alberta | Cross Cancer Institute | Edmonton |
| Canada, Nova Scotia | Dalhousie University | Halifax |
| Canada, Ontario | Princess Margaret Hospital University Health Network | Toronto |
| Canada, Quebec | McGill University Health Center (MUHC) | Montreal |
| Spain | Hospital Germans Trias I Pujol | Badalona |
| Spain | Clinica Universidad de Navarra | Pamplona |
| Spain | Hospital Universitario de Salamanca | Salamanca |
| Spain | Hospital Universtario Marques de Valdecilla | Santander |
| Sweden | Sahlgrenska Universitetssjukhus | Göteborg |

**Sponsors and Collaborators**

Celgene

**Investigator**

| | | |
|---|---|---|
| Study Director : | Bristol-Myers Squibb | Bristol-Myers Squibb |

---

**MORE INFORMATION**

| | |
|---|---|
| **Responsible Party :** | Celgene |
| **ClinicalTrials.gov Identifier :** | NCT04975399 |
| **Other Study ID Numbers :** | CC-92328-MM-001, 2020-005968-64 |
| **First Posted :** | July 23, 2021 |
| **Last Update Posted :** | February 7, 2022 |
| **Last Verified :** | February 2022 |
| **Individual Participant Data (IPD) Sharing Statement:** | |
| **Plan to Share IPD:** | Yes |
| **Plan Description:** | Information relating to our policy on data sharing and the process for requesting data can be found at the following link: https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/ |
| **Supporting Materials:** | Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR), Analytic Code |
| **Time Frame:** | See Plan Description |
| **Access Criteria:** | See Plan Description |
| **URL:** | https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/ |
| **Studies a U.S. FDA-regulated Drug Product:** | Yes |
| **Studies a U.S. FDA-regulated Device Product:** | No |
| **Keywords provided by Celgene:** | *Multiple Myeloma*<br>*First-in-human*<br>*Phase 1 Relapsed or Refractory*<br>*CC-92328* |

**Additional relevant MeSH terms :**

| | |
|---|---|
| *Multiple Myeloma* | *Paraproteinemias* |
| *Neoplasms, Plasma Cell* | *Blood Protein Disorders* |
| *Neoplasms by Histologic Type* | *Hematologic Diseases* |
| *Neoplasms* | *Hemorrhagic Disorders* |
| *Hemostatic Disorders* | *Lymphoproliferative Disorders* |
| *Vascular Diseases* | *Immunoproliferative Disorders* |
| *Cardiovascular Diseases* | *Immune System Diseases* |