A Study of CC-95266 in Subjects With Relapsed and/or Refractory Multiple Myeloma

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT04674813	RECRUITING	DECEMBER 19, 2020	SEPTEMBER 23, 2021

STUDY DESCRIPTION

Brief Summary

This is a Phase 1, multicenter, open label, study of CC-95266 in subjects with relapsed and/or refractory multiple myeloma. The study will consist of two parts: dose escalation (Part A) and dose expansion (Part B). The dose escalation (Part A) of the study will evaluate the safety and tolerability of increasing doses of CC-95266 in a single administration to establish a maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), and the dose expansion (Part B) of the study will further evaluate the safety, pharmacokinetics (PK)/ pharmacodynamics (PD), and efficacy of CC-95266 at the RP2D.

Condition or Disease: Multiple Myeloma

Intervention/treatment: Drug: CC-95266
Drug: Fludarabine
Drug: Cyclophosphamide

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 77 participants

Intervention Model : Single Group Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Phase 1, Multicenter, Open-Label Study of CC-95266 in Subjects With Relapsed and/or Refractory Multiple Myeloma

Actual Study Start Date: February 2021

Estimated Primary Completion Date: June 2025

Estimated Study Completion Date: June 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Administration of CC-95266 Subjects will receive CC-95266 after completion of lymphodepleting (LD) chemotherapy (fludarabine and cyclophosphamide)	Drug: CC-95266 IV Drug: Fludarabine IV Drug: Cyclophosphamide IV

OUTCOME MEASURES

Primary Outcome Measures:
1. Adverse Events (AEs) [Time Frame: Up to 2 years after CC-95266 infusion]
An AE is any noxious, unintended, or untoward medical occurrence that may appear or worsen in a subject during the course of a study. It may be a new intercurrent illness, a worsening concomitant illness, an injury, or any concomitant impairment of the subject's health, including laboratory test values, regardless of etiology. Any worsening (ie, any clinically significant adverse change in the frequency or intensity of a preexisting condition) should be considered an AE.
2. Maximum Tolerated Dose (MTD) [Time Frame: Up to 2 years after CC-95266 infusion]
MTD is defined as the dose level that can be given such that the estimated DLT probability is closest to approximately 30%
3. Recommended Phase 2 Dose (RP2D) [Time Frame: Up to 2 years after CC-95266 infusion]
RP2D is defined as the dose recommended for further investigation in a Phase 2 study

Secondary Outcome Measures:
1. Pharmacokinetics - Cmax [Time Frame: Up to 2 years after CC-95266 infusion]
Cmax is defined as maximum plasma concentration of drug
2. Pharmacokinetics - tmax [Time Frame: Up to 2 years after CC-95266 infusion]
tmax is defined as time to peak (maximum) serum concentration
3. Pharmacokinetics - AUC(1-29) [Time Frame: Up to 2 years after CC-95266 infusion]
AUC(1-29) is defined as area under the curve for days 1-29 after CC-95266 infusion
4. Overall response rate (ORR) [Time Frame: Up to 2 years after CC-95266 infusion]
ORR is defined as proportion of subjects achieving sCR, CR, VGPR, or PR
5. Complete response rate (CRR) [Time Frame: Up to 2 years after CC-95266 infusion]
CRR is defined as proportion of subjects with sCR or CR
6. Duration of response (DOR) [Time Frame: Up to 2 years after CC-95266 infusion]
DOR is defined as the time from first response (sCR, CR, VGPR, or PR) to PD or death
7. Duration of complete response (DOCR) [Time Frame: Up to 2 years after CC-95266 infusion]
DOCR is defined as a best overall response of sCR or CR, time from first response (sCR, CR, VGPR, or PR) to the first documentation of PD or death

8. Time to response (TTR) [Time Frame: Up to 2 years after CC-95266 infusion]
TTR is defined as time from CC-95266 infusion to the first documentation of response (sCR, CR, VGPR, or PR)
9. Time to complete response (TTCR) [Time Frame: Up to 2 years after CC-95266 infusion]
TTCR is defined as time from CC-95266 infusion to the first documentation of sCR or CR
10. Progression-free survival (PFS) [Time Frame: Up to 2 years after CC-95266 infusion]
PFS is defined as time from CC-95266 infusion to the first documentation of PD, or death from any cause, whichever occurs first
11. Overall survival (OS) [Time Frame: Up to 2 years after CC-95266 infusion]
OS is defined as time from CC-95266 infusion to death

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:
Age ≥ 18 years. Signed written informed consent prior to any study procedure. Subject has a diagnosis of multiple myeloma with relapsed and/or refractory disease. Subjects must have documented progressive disease on or within 12 months of completing treatment with the last anti-myeloma treatment regimen, except for subjects with cellular therapy (eg, CAR T-cell therapy) as their last treatment, who may enroll beyond 12 months.
Subjects must have received at least 3 prior anti-myeloma treatment regimens (note: induction with or without HSCT and with or without maintenance therapy is considered one regimen), including:
Autologous stem cell transplant A regimen that included an immunomodulatory agent (eg, thalidomide, lenalidomide, pomalidomide) and a proteasome inhibitor (eg, bortezomib, carfilzomib, ixazomib), either alone or combination Anti-CD38 (eg, daratumumab), either alone or combination Measurable disease Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 Adequate organ function
Exclusion Criteria:
Known active or history of central nervous system (CNS) involvement of MM Active or history of plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, or clinically significant amyloidosis Uncontrolled or active infection Active autoimmune disease requiring immunosuppressive therapy History or presence of clinically significant CNS pathology such as seizure disorder, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

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CONTACTS AND LOCATIONS

Contacts

Contact: Associate Director Clinical Trial Disclosure 1-888-260-1599 clinicaltrialdisclosure@celgene.com

Locations

United States, Alabama	University of Alabama Birmingham	Birmingham
United States, California	City of Hope	Duarte
United States, Colorado	Colorado Blood Cancer Institute	Denver
United States, Maryland	University of Maryland - Greenebaum Comprehensive Cancer Center	Baltimore
United States, Massachusetts	Dana Farber Cancer Institute	Boston
United States, New York	Icahn School of Medicine at Mount Sinai Medical Center	New York
United States, Tennessee	Sarah Cannon Research Institute Center for Blood Cancers	Nashville
United States, Texas	Southwestern Medical Center- Harold C Simmons Comprehensive Cancer Center	Dallas
United States, Washington	Swedish Cancer Institute	Seattle

Sponsors and Collaborators

Juno Therapeutics, a Subsidiary of Celgene

Investigator

Study Director :	Allison Kaeding, MD	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Juno Therapeutics, a Subsidiary of Celgene
ClinicalTrials.gov Identifier :	NCT04674813
Other Study ID Numbers :	CC-95266-MM-001, U1111-1260-4921
First Posted :	December 19, 2020
Last Update Posted :	September 23, 2021
Last Verified :	September 2021

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 Juno Therapeutics, a Subsidiary of Celgene:	*CC-95266* *Multiple Myeloma Relapsed and/or Refractory*

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*