A Study of CC-95251, a Monoclonal Antibody Directed Against SIRPα, in Participants With Advanced Solid and Hematologic Cancers

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03783403	RECRUITING	DECEMBER 21, 2018	JUNE 16, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to evaluate the safety, tolerability, and preliminary clinical activity of CC-95251 as a single agent and in combination with cetuximab and rituximab in participants with advanced solid and hematologic cancers.

Condition or Disease: Neoplasms

Intervention/treatment: Drug: CC-95251
Drug: Rituximab
Drug: Cetuximab

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 230 participants

Intervention Model : Single Group Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study of CC-95251, a Monoclonal Antibody Directed Against SIRPα, in Participants With Advanced Solid and Hematologic Cancers

Actual Study Start Date: February 2019

Estimated Primary Completion Date: June 2024

Estimated Study Completion Date: August 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: CC-95251	Drug: CC-95251 Specified dose on specified days
Experimental: CC-95251 in combination with cetuximab	Drug: CC-95251 Specified dose on specified days Drug: Cetuximab Specified dose on specified days
Experimental: CC-95251 in combination with rituximab	Drug: CC-95251 Specified dose on specified days Drug: Rituximab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Non-Tolerated Dose (NTD): A dose that causes unacceptable side effects [Time Frame: 18 months]
2. Maximum Tolerated Dose (MTD): The highest dose that does not cause unacceptable side effects [Time Frame: 18 months]
3. Dose-Limiting Toxicity (DLT): Any adverse events meeting the protocol-defined DLT criteria [Time Frame: 30 months]

Secondary Outcome Measures:
1. Overall response rate (ORR): The percent of participants whose best response is complete response (CR) or partial response (PR) [Time Frame: 72 Months]
2. Time to response (TTR): Time from the first dose to the first objective tumor response observed for participants who achieved a CR or PR [Time Frame: 66 Months]
3. Duration of response (DOR): Time from the first objective tumor response observed for participants who achieved a CR or PR until the first date at progressive disease is objectively documented [Time Frame: 66 Months]
4. Progression free survival (PFS): Time from the first dose to the first occurrence of disease progression or death from any cause [Time Frame: 66 Months]
5. Overall survival (OS): Time from the first dose to death due to any cause [Time Frame: 66 Months]
6. Pharmacokinetic - Maximum serum concentration of the drug (Cmax) [Time Frame: 36 Months]
7. Pharmacokinetic - Minimum serum concentration of the drug (Cmin) [Time Frame: 36 Months]
8. Pharmacokinetic - Area under the serum concentration time-curve of the drug (AUC) [Time Frame: 36 Months]
9. Anti-CC-95251 antibody (ADA) assessment: determine the presence and frequency of anti-drug antibodies [Time Frame: 36 Months]

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:
Progressed on standard anticancer therapy or for whom no other approved conventional therapy exists and have histological or cytological confirmation of advanced unresectable solid tumors, advanced unresectable colorectal cancer, or squamous cell carcinoma of the head and neck, or CD20-positive non-Hodgkin's lymphoma, or diffuse large B cell lymphoma, or follicular lymphoma Solid tumors must have at least one site of measurable disease as determined by RECIST v1.1 Eastern cooperative oncology group performance status of 0 or 1
Exclusion Criteria:
High-grade lymphomas (Burkitt's or lymphoblastic) Has cancer with symptomatic central nervous system (CNS) involvement History of class III or IV congestive heart failure (CHF) or severe non-ischemic cardiomyopathy, unstable angina, myocardial infarction, or ventricular arrhythmia within the previous 6 months Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center www.BMSStudyConnect.com 855-907-3286 Clinical.Trials@bms.com
Contact: First line of the email MUST contain the NCT# and Site #.

Locations

United States, Alabama	University of Alabama Birmingham	Birmingham
United States, Arizona	HonorHealth Research Institute	Scottsdale
United States, California	UC Davis Medical Center	Sacramento
United States, California	UC Davis Medical Center	Sacramento
United States, Missouri	Washington University School of Medicine	Saint Louis
United States, Missouri	Washington University School Of Medicine	Saint Louis
United States, New York	NYU Langone Laura and Isaac Perlmutter Cancer Center	New York
United States, New York	NYU Langone Laura and Isaac Perlmutter Cancer Center	New York
United States, North Carolina	Levine Cancer Institute	Charlotte
United States, Oklahoma	University of Oklahoma Peggy and Charles Stephenson Cancer Center	Oklahoma City
United States, Oklahoma	University of Oklahoma Peggy and Charles Stephenson Cancer Center	Oklahoma City
United States, Oregon	Providence Cancer Center/Earle A. Chiles Res. Inst.	Portland
United States, Pennsylvania	University of Pittsburgh Medical Center - Cancer Pavilion	Pittsburgh
United States, Pennsylvania	University of Pittsburgh Medical Center - Cancer Pavilion	Pittsburgh
United States, Tennessee	Tennessee Oncology	Nashville
United States, Tennessee	Tennessee Oncology	Nashville
United States, Texas	The University of Texas - MD Anderson Cancer Center	Houston
United States, Texas	The University of Texas - MD Anderson Cancer Center	Houston
United States, Texas	South Texas Accelerated Research Therapeutics	San Antonio
United States, Texas	South Texas Accelerated Research Therapeutics	San Antonio
Australia, Victoria	Austin Health - Austin Hospital	Heidelberg
Australia, Victoria	Local Institution - 301	Heidelberg
Australia, Victoria	Peter MacCallum Cancer Centre	Melbourne
Canada, Alberta	Cross Cancer Institute	Edmonton
Canada, Alberta	Local Institution - 201	Edmonton
Canada, Ontario	Princess Margaret Cancer Centre	Toronto
France	Institut Bergonie	Borddeaux Cedex
France	Local Institution - 402	Borddeaux Cedex

France	Hôpital Henri Mondor	Creteil
France	Local Institution - 406	Creteil
France	Unité Lymphoïde - Hématologie 4-IPC4	Marseille
France	Hotel Dieu CHU Nantes	Nantes Cedex 01
France	Local Institution - 404	Nantes Cedex 01
France	CLCC H BecquerelHematology	Rouen
France	Local Institution - 403	Rouen
France	Gustave Roussy	Villejuif CEDEX
France	Local Institution - 401	Villejuif CEDEX
Italy	Istituto di Ematologia L. e A. Seragnoli-Azienda Ospedaliero Universitaria Policlinico S. Orsola M	Bologna
Italy	Istituto Nazionale Per Lo Studio E La Cura Dei Tumori Fondazione Giovanni Pascale	Napoli, Campania
Korea, Republic of	Local Institution - 604	Seoul
Korea, Republic of	Severance Hospital	Seoul
Korea, Republic of	Samsung Medical Center	Seoul
Korea, Republic of	Local Institution - 602	Seoul
Korea, Republic of	Seoul National University Hospital	Seoul
Korea, Republic of	Asan Medical Center	Seoul
Korea, Republic of	Local Institution - 601	Seoul
Spain	Hospital Universitario Fundacion Jimenez Diaz	Madrid
Spain	Hospital Universitario Virgen De La Victoria	Malaga
Spain	Local Institution - 502	Malaga
Spain	Local Institution - 501	Salamanca
Spain	Universitario de Salamanca - Hospital Clinico	Salamanca
United Kingdom	Derriford Hospital, University Hospitals Plymouth NHS Trust	Crownhill, Plymouth
United Kingdom	Royal Marsden Hospital	London
United Kingdom	Christie NHS Trust	Manchester

Sponsors and Collaborators

Celgene

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Celgene
ClinicalTrials.gov Identifier :	NCT03783403
Other Study ID Numbers :	CC-95251-ST-001, NCT03816254, U1111-1224-8251
First Posted :	December 21, 2018
Last Update Posted :	June 16, 2022
Last Verified :	June 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Celgene:	*Antibody* *CC-95251* *SIRPα Advanced Solid Cancers* *Advanced Hematologic Cancers*
Additional relevant MeSH terms :	*Neoplasms* *Neoplasms by Site* *Hematologic Neoplasms* *Hematologic Diseases*