A Safety and Efficacy Study of CC-90011 in Participants With Relapsed and/or Refractory Solid Tumors and Non-Hodgkin's Lymphomas

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT02875223	RECRUITING	AUGUST 23, 2016	MAY 27, 2022

STUDY DESCRIPTION

Brief Summary

Study CC-90011-ST-001 is an open-label, Phase 1, dose escalation and expansion, First-In-Human (FIH) clinical study of CC-90011 in subjects with advanced unresectable solid tumors (enriched for grade 2 NENs, grade 2 NETs and NECs) and R/R NHL (MZL, including extranodal MZL [EMZL], splenic MZL [SMZL], nodal MZL [NMZL], and histologic transformation of MZL). The dose escalation part (Part A) of the study will explore escalating oral doses of CC-90011 to estimate the maximum tolerated dose (MTD) of CC-90011. The expansion part (Part B) will further evaluate the safety and efficacy of CC-90011 administered at or below the MTD in 3 selected expansion cohorts of approximately 10-20 evaluable subjects each, in order to further define the RP2D.

Condition or Disease: Lymphoma, Non-Hodgkin
Neoplasms

Intervention/treatment: Drug: CC-90011
Drug: Rifampicin
Drug: Itraconazole

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 91 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Safety and Efficacy Study of CC-90011 in Participants With Relapsed and/or Refractory Solid Tumors and Non-Hodgkin's Lymphomas

Actual Study Start Date: August 2016

Estimated Primary Completion Date: August 2023

Estimated Study Completion Date: June 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: CC-90011 and Itraconazole	Drug: CC-90011 Specified dose on specified days Drug: Itraconazole Specified dose on specified days
Experimental: CC-90011 and Rifampicin	Drug: CC-90011 Specified dose on specified days Drug: Rifampicin Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Dose-Limiting Toxicity (DLT) [Time Frame: Up to approximately 28 days]
Number of participants with DLT
2. Maximum tolerated dose (MTD) evaluated using the NCI CTCAE criteria [Time Frame: Up to approximately 28 days]
3. Maximum observed plasma concentration (Cmax) [Time Frame: Up to approximately 9 years]
4. Area under the plasma concentration-time curve (AUC) from time zero extrapolated to infinity (AUC0-∞) [Time Frame: Up to approximately 9 years]
5. AUC from time zero to the last quantifiable concentration (AUC0-t) [Time Frame: Up to approximately 9 years]

Secondary Outcome Measures:
1. Clinical Benefit Rate (CBR) determined by response and stable disease rates by disease appropriate response criteria [Time Frame: Up to approximately 8 years]
Is defined as tumor responses (as assessed by the Investigators) of complete response (CR), partial response (PR) and durable stable disease (SD) (SD of ≥ 4 months duration)
2. Objective Response Rate (ORR) [Time Frame: Up to approximately 8 years]
Is defined as the percent of subjects whose best response is complete response (CR) or partial response (PR)
3. Progression-Free Survival (PFS) [Time Frame: Up to approximately 8 years]
Is defined as the time from the first dose of CC-90011 to the first occurrence of disease progression or death from any cause

4. Overall Survival (OS) [Time Frame: Up to approximately 8 years]
Is measured as the time from the first dose of CC-90011 to death due to any cause
5. Duration of Response (DOR) [Time Frame: Up to approximately 8 years]

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:
Advanced or unresectable solid tumors including those who have progressed on (or not been able to tolerate due to medical comorbidities or unacceptable toxicity) standard anticancer therapy or for whom no other approved conventional therapy exists Eastern Cooperative Oncology Group Performance Status of 0 to 1
Exclusion Criteria:
Prior autologous stem cell transplant ≤ 3 months before first dose or those who have not recovered Symptomatic or uncontrolled ulcers (gastric or duodenal), particularly those with a history of and/or risk of perforation and gastrointestinal tract hemorrhages Impaired cardiac function or clinically significant cardiac diseases Poor bone marrow reserve as assessed by Investigator
Refer to protocol defined exclusion criteria for parts C and D. 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

France	Centre Georges Francois Leclerc	Dijon
France	Institut Paoli Calmettes	Marseille Cedex 9
France	Gustave Roussy	Villejuif Cedex
Italy	Bologna University	Bologna
Italy	Istituto Nazionale Dei Tumori	Milano
Italy	Istituto Europeo di Oncologia	Milano
Japan, Tokyo	Local Institution - 501	Chuo-ku
Japan, Tokyo	National Cancer Center Hospital	Chuo-ku
Japan, Tokyo	The Cancer Institute Hospital of Japanese Foundation For Cancer Research	Koto-ku
Japan, Tokyo	Local Institution - 502	Koto
Japan	Local Institution - 500	Kashiwa
Japan	National Cancer Center Hospital East	Kashiwa
Spain	Hospital Universitario Vall D hebron - PPDS	Barcelona
Spain	Fundacion Jimenez Daaz	Madrid
Spain	Hospital 12 de Octubre	Madrid
Spain	Hospital Universitario Marques de Valdecilla	Santander
United Kingdom	Local Institution - 300	London
United Kingdom	Royal Marsden Hospital	London
United Kingdom	Freeman Hospital	Newcastle Upon Tyne

Sponsors and Collaborators

Celgene

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

	Hollebecque A, Salvagni S, Plummer R, Isambert N, Niccoli P, Capdevila J, Curigliano G, Moreno V, Martin-Romano P, Baudin E, Arias M, Mora S, de Alvaro J, Di Martino J, Parra-Palau JL, Sánchez-Pérez T, Aronchik I, Filvaroff EH, Lamba M, Nikolova Z, de Bono JS. Phase I Study of Lysine-Specific Demethylase 1 Inhibitor, CC-90011, in Patients with Advanced Solid Tumors and Relapsed/Refractory Non-Hodgkin Lymphoma. Clin Cancer Res. 2021 Jan 15;27(2):438-446. doi: 10.1158/1078-0432.CCR-20-2380. Epub 2020 Oct 12.
Responsible Party :	Celgene
ClinicalTrials.gov Identifier :	NCT02875223
Other Study ID Numbers :	CC-90011-ST-001
First Posted :	August 23, 2016
Last Update Posted :	May 27, 2022
Last Verified :	May 2022
Keywords provided by Celgene:	*Safety* *CC-90011* *Advanced unresectable solid Tumors Low intermediate-grade lung neuroendocrine tumors (Typical and Atypical carcinoids)* *Neuroendocrine prostate cancer (NEPC)* *R/R Non-Hodgkin's Lymphomas*
Additional relevant MeSH terms :	*Lymphoma* *Lymphoma, Non-Hodgkin* *Neoplasms by Histologic Type* *Neoplasms* *Lymphoproliferative Disorders* *Lymphatic Diseases* *Immunoproliferative Disorders* *Immune System Diseases*