A Study to Evaluate the Safety, Tolerability, Drug Levels, and Preliminary Efficacy of Relatlimab Plus Nivolumab in Pediatric and Young Adults With Hodgkin and Non-Hodgkin Lymphoma

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05255601	NOT YET RECRUITING	FEBRUARY 24, 2022	MAY 3, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to assess the safety, tolerability, drug levels, and preliminary efficacy of relatlimab plus nivolumab in pediatric and young adult participants with recurrent or refractory classical Hodgkin lymphoma and non-Hodgkin lymphoma.

Condition or Disease: Lymphoma, Non-Hodgkin
Hodgkin Disease

Intervention/treatment: Drug: Relatlimab
Drug: Nivolumab

Phase: Phase 1/Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 68 participants

Allocation : Non-Randomized

Intervention Model : Sequential Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study to Evaluate the Safety, Tolerability, Drug Levels, and Preliminary Efficacy of Relatlimab Plus Nivolumab in Pediatric and Young Adults With Hodgkin and Non-Hodgkin Lymphoma

Estimated Study Start Date: June 2022

Estimated Primary Completion Date: July 2027

Estimated Study Completion Date: April 2030

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Relatlimab + Nivolumab	Drug: Relatlimab Specified Dose on Specified Days Drug: Nivolumab Specified Dose on Specified Days

OUTCOME MEASURES

Primary Outcome Measures:
1. Incidence of dose-limiting toxicities (DLTs) [Time Frame: Up to 100 days following last dose]
2. Maximum tolerated dose or Recommended phase 2 dose (MTD/RP2D) [Time Frame: Up to 100 days following last dose]
3. Number of participants with Adverse Events (AEs) [Time Frame: Up to 100 days following last dose]
4. Number of participants with serious adverse events (SAEs) [Time Frame: Up to 100 days following last dose]
5. Number of participants with AEs leading to discontinuation [Time Frame: Up to 100 days following last dose]
6. Number of deaths [Time Frame: Up to 100 days following last dose]
7. Number of participants with clinical laboratory abnormalities [Time Frame: Up to 100 days following last dose]
8. Maximum observed plasma concentration (Cmax) [Time Frame: Up to 96 weeks]
9. Trough observed concentration (Ctrough) [Time Frame: Up to 96 weeks]
10. Time of maximum observed plasma concentration (Tmax) [Time Frame: Up to 96 weeks]
11. Area Under the Curve within a dosing interval (AUC(TAU)) [Time Frame: Up to 96 weeks]
12. Complete Metabolic Response (CMR) Rate defined as the proportion of all response-evaluable participants who achieve the best response of CMR using Lugano 2014 criteria [Time Frame: Up to 32 weeks following first dose]

Secondary Outcome Measures:
1. Number of participants with AEs [Time Frame: Up to 100 days following last dose]
2. Number of participants with SAEs [Time Frame: Up to 100 days following last dose]
3. Number of participants with AEs leading to discontinuation [Time Frame: Up to 100 days following last dose]
4. Number of deaths [Time Frame: Up to 100 days following last dose]
5. Number of participants with clinical laboratory abnormalities [Time Frame: Up to 100 days following last dose]
6. Overall Response Rate (ORR) defined as the proportion of all response- evaluable participants who achieve a best response of CMR or partial metabolic response (PMR) using the Lugano 2014 classification [Time Frame: Up to 32 weeks following first dose]

ELIGIBILITY CRITERIA

Ages Eligible for Study: up to 30 / (18 to 64 years)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Pathologically confirmed high-risk recurrent/relapsed or refractory (R/R) classical Hodgkin lymphoma (cHL), after non-response to or failure of first-line standard therapy prior to high-dose chemotherapy/autologous stem cell transplant (HDCT/ASCT) Pathologically confirmed high-risk, R/R non-Hodgkin lymphoma (NHL) after failure or non-response to first-line therapy, including but not limited to diffuse large B-cell lymphoma (DLBCL), anaplastic large cell lymphoma (ALCL) and primary mediastinal B-cell lymphoma Pathologically confirmed recurrent cHL or NHL Must have measurable [18F]fluorodeoxyglucose-positron emission tomography-computed tomography (FDG-PET-CT) positive disease in both cHL and NHL cohorts
Exclusion Criteria:
Prior treatment with an anti-cytotoxic T-lymphocyte-associated protein 4 (anti-CTLA-4) antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways, with the exception of anti-PD(L)-1 targeted therapies Prior treatment with lymphocyte activation gene-3 (LAG-3)-targeted agents Prior autologous stem cell transplantation (HDCT/ASCT) History of allogeneic bone marrow transplantation and with active graft versus host disease (GVHD) and prior history of Grade > 2 GVHD
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 NCT # and Site #.

Locations

United States, Arizona	Local Institution	Phoenix
United States, Florida	Local Institution	Orlando
United States, Florida	Local Institution	West Palm Beach
United States, Minnesota	Local Institution	Minneapolis
United States, Mississippi	Local Institution	Jackson
United States, Missouri	Local Institution	Saint Louis
United States, New York	Local Institution	Bronx
United States, New York	Local Institution	Valhalla
United States, Pennsylvania	Local Institution	Hershey
United States, Tennessee	Local Institution	Nashville
United States, Texas	Local Institution	Austin
United States, Texas	Local Institution	San Antonio
Australia, Western Australia	Local Institution	Nedlands
France	Local Institution	Bordeaux
France	Local Institution	Lyon
France	Local Institution	Montpellier
France	Local Institution	Paris
France	Local Institution	Paris
France	Local Institution - 0022	Rennes
France	Local Institution	Strasbourg
Germany	Local Institution	Aachen
Germany	Local Institution	Berlin
Germany	Local Institution	Giessen
Germany	Local Institution	Muenster
Germany	Local Institution	Munich
Italy	Local Institution	Aviano

Italy	Local Institution	Bologna
Italy	Local Institution	Florence
Italy	Local Institution	Genoa
Italy	Local Institution	Milano
Italy	Local Institution	Monza
Italy	Local Institution	Napoli
Italy	Local Institution	Pavia
Italy	Local Institution	Roma
Italy	Local Institution	Turin
Netherlands	Local Institution	Utrecht
Spain	Local Institution	Barcelona
Spain	Local Institution	Barcelona
Spain	Local Institution	Madrid
Spain	Local Institution	Madrid
Spain	Local Institution	Madrid
Spain	Local Institution	Madrid
Spain	Local Institution	Madrid
Spain	Local Institution	Santander
Spain	Local Institution	Sevilla
Spain	Local Institution	Valencia
United Kingdom	Local Institution	Birmingham
United Kingdom	Local Institution	Bristol
United Kingdom	Local Institution	London
United Kingdom	Local Institution	Nottingham
United Kingdom	Local Institution	Sutton

Sponsors and Collaborators

Bristol-Myers Squibb

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT05255601
Other Study ID Numbers :	CA224-069, 2021-000493-29, U1111-1264-4062
First Posted :	February 24, 2022
Last Update Posted :	May 3, 2022
Last Verified :	April 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Bristol-Myers Squibb:	*Pediatric* *Lymphoma, Non-Hodgkin* *Hodgkin Disease* *Relatlimab* *Nivolumab Lymphocyte Activation Gene-3* *Lymphoma, Large B-Cell, Diffuse* *Primary Mediastinal B-cell Lymphoma* *Lymphoma, Large-Cell, Anaplastic*

Additional relevant MeSH terms :	*Lymphoma*	*Lymphoproliferative Disorders*
	Lymphoma, Non-Hodgkin	*Lymphatic Diseases*
	Hodgkin Disease	*Immunoproliferative Disorders*
	Neoplasms by Histologic Type	*Immune System Diseases*
	Neoplasms	