A multicenter, randomized, open-label Phase 2 study evaluating the safety and efficacy of three different regimens of oral panobinostat in combination with subcutaneous bortezomib and oral dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma who have been previously exposed to immunomodulatory agents

14/12/2025 16:47:20

Main Information

Primary registry identifying number
LBCTR2019010183

Protocol number
CLBH589D2222

MOH registration number
5241/ص

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
LCTR was already initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
12/07/2016

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
11/06/2019

Date of registration in national regulatory agency
12/07/2016

Public title
A multicenter, randomized, open-label Phase 2 study evaluating the safety and efficacy of three different regimens of oral panobinostat in combination with subcutaneous bortezomib and oral dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma who have been previously exposed to immunomodulatory agents

Acronym
PANORAMA 3

Scientific title
"A multicenter, randomized, open-label Phase 2 study evaluating the safety and efficacy of three different regimens of oral panobinostat in combination with subcutaneous bortezomib and oral dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma who have been previously exposed to immunomodulatory agents"

Acronym

Brief summary of the study: English

Brief Summary:

The purpose of this study is to investigate the safety and efficacy of three different regimens of PAN (20 mg TIW, 20 mg BIW, and 10 mg TIW) in combination with s.c. BTZ and Dex and to provide exposure, safety and efficacy data to identify the optimal regimen of PAN in a randomized, 3-arm parallel design. This study will also assess the impact of administering s.c. BTZ (in combination with PAN and Dex) twice weekly for 4 cycles, and then weekly starting from Cycle 5 until disease progression in patients ≤ 75 years of age. Patients > 75 years of age will receive for the entire treatment period s.c. BTZ weekly (in combination with PAN and Dex) until disease progression.

Patients will be treated until disease progression or until they discontinue earlier due to unacceptable toxicity or for other reasons.

Patients who discontinued study treatment for reasons other than disease progression will be followed for efficacy every 6 weeks.

All patients will be followed for survival until the last patient entering long-term follow-up has completed a 3 year survival follow-up or discontinued earlier.

Brief summary of the study: Arabic

دراسة مرحلة ثانية متعددة المراكز و عشوائيّة التوزيع ومفتوحة اللصاقة
لتقييم سلامة وفعاليّة ثلاثة أنظمة علاجيّة مختلفة من بانوبينوستات عن طريق الفم بالاشتراك مع بورتيزوميب تحت الجلد وديكساميثازون عن طريق الفم لدى مرضى مصابين بالورم النقوي المتعدد المعاود أو المعاود/المقاوم للعلاج تعرّضوا في السابق لأدوية مناعيّة مكيّفة

Health conditions/problem studied: Specify

Patient with Relapsed or Relapsed-and-refractory Multiple Myeloma

Interventions: Specify

Drug: Panobinostat capsules
Drug: bortezomib injection
Drug: dexamethasone tablets

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:
•multiple myeloma as per IMWG 2014 definition
•requiring treatment for relapsed or relapsed/refractory disease
•measurable disease based on central protein assessment
•1 to 4 prior lines of therapy
•prior IMiD exposure
•acceptable lab values prior to randomization

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:
•primary refractory myeloma
•refractory to bortezomib
•concomitant anti-cancer therapy (other then BTZ/Dex and bisphosphonates
•prior treatment with DAC inhibitors
•Clinically significant, uncontrolled heart disease and/or recent cardiac event (within 6 months prior to randomization)
•Unresolved diarrhea ≥ CTCAE grade 2 or presence of medical condition associated with chronic diarrhea (such as irritable bowel syndrome, inflammatory bowel disease)

Other protocol-defined inclusion/exclusion criteria may apply.

Type of study

Interventional

Type of intervention
Pharmaceutical

Type of intervention: Specify type
N/A

Trial scope
Other

Trial scope: Specify scope

Study design: Allocation
Randomized controlled trial

Study design: Masking
Open (masking not used)

Study design: Control
Dose comparison

Study phase
2

Study design: Purpose
Treatment

Study design: Specify purpose
N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization
Yes, Worldwide

IMP has market authorization: Specify
Both US FDA and EU approved

Name of IMP
Panobinostat (FARYDAK)

Year of authorization
2015

Month of authorization
2

Type of IMP
Others

Pharmaceutical class
Panobinostat has been developed as a pan-HDAC inhibitor of Class I, II and IV histone deacetylases (HDACs) involved in the deacetylation of histone and non-histone cellular proteins.

Therapeutic indication
patients with relapsed or relapsed/refractory multiple myeloma

Therapeutic benefit
Overall response rate (ORR) up to 8 cycles

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Samples will be sent to Covance central Lab in Switzerland as per study protocol to assess patient disease response following treatment administration.

Target sample size

8

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

10/05/2017

Date of study closure: Type

Actual

Date of study closure: Date

04/02/2020

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

Additional data URL

https://clinicaltrials.gov/ct2/show/NCT02654990?term=clbh589d2222&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
National Institute of Health (clinicaltrials.gov)	NCT02654990

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Fadi Farhat	Saida	Lebanon	+961 3 753 155	drfadi.trials@gmail.com	Hammoud Hospital
Scientific	Hind Khairallah	Beirut	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Fadi El Karak	Mansourieh	Lebanon	+961 3 061 621	felkarak@yahoo.com	Bellevue Medical Center
Public	Joseph Kattan	Beirut	Lebanon	+961 1424942	jkattan62@hotmail.com	Hotel Dieu De France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital	Dr Fadi Farhat	Hematology Oncology	Approved
Bellevue Medical Center	Dr Fadi El Karak	Hematology Oncology	Approved
Hotel Dieu De France	Dr Joseph Kattan	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	07/04/2016	Joseph Kattan	jkattan62@hotmail.com	009613635913
Bellevue Medical Center	22/08/2016	Fadi El Karak	felkarak@yahoo.com	00961 3 061 621
Hammoud Hospital University Medical Center	08/05/2017	Fadi Farhat	drfadi.trials@gmail.com	00961 3 753 155

Countries of Recruitment

Name
Lebanon
Republic of Korea
Netherlands
Norway
Poland
Portugal
Russian Federation
Spain
Sweden
Thailand
Australia
Belgium
Brazil
Canada
Czech Republic
France
Germany
Greece
Hungary
Italy
Turkey
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Multiple myeloma	Multiple myeloma (C90.0)	MM

Interventions

Intervention	Description	Keyword
Reference table 7.1 of the study protocol: History taking/ Lab procedures/ Radiology assessment/ medication administration/ ECG / Questionnaire completion/ Bone marrow aspirate procedure/ Assessment of adverse events	Informed consent form	ICF/ Blood test/ Vital signs

Primary Outcomes

Name	Time Points	Measure
1.Overall response rate (ORR) up to 8 cycles	[Time Frame: up to 8 cycles per patient, approximately 30 months]	up to 8 cycles

Key Secondary Outcomes

Name	Time Points	Measure
overall response rate	through out study	Through out the study
Progression-free survival	Progression free survival	PFS

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files