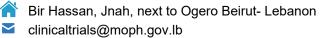
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Study Assessing the Efficacy and Safety of Alpelisib + Nabpaclitaxel in Subjects With Advanced TNBC Who Carry Either a PIK3CA Mutation or Have PTEN Loss Without PIK3CA Mutation

20/08/2025 09:27:51

Primary registry identifying number	Protocol number
LBCTR2021044784	CBYL719H12301
LBC1R2021044764	
MOH registration number	
Study registered at the country of origin	Study registered at the country of origin: Specify
Yes	
Type of registration	Type of registration: Justify
Prospective	N/A
Date of registration in national regulatory agency	
Primary sponsor	Primary sponsor: Country of origin
Novartis Pharma Services inc.	Novartis Pharmaceuticals
Date of registration in primary registry	Date of registration in national regulatory agency
06/06/2022	
Public title	Acronym
Study Assessing the Efficacy and Safety of Alpelisib + Nab- paclitaxel in Subjects With Advanced TNBC Who Carry Either a PIK3CA Mutation or Have PTEN Loss Without PIK3CA Mutation	
Scientific title	Acronym
A Phase III, Multicenter, Randomized, Double-blind, Placebo- controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Nab-paclitaxel in Patients With Advanced Triple Negative Breast Cancer With Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation	
Brief summary of the study: English	
The purpose of this study is to determine whether treatment with alpelisib in combination with nab-paclitaxel is safe and effective in subjects with advanced triple negative breast cancer (aTNBC) who carry either a PIK3CA mutation (Study Part A) or have PTEN loss without PIK3CA mutation (Study Parts B1 and B2)	
Brief summary of the study: Arabic	
مزدوجة التعمية، مرتكزة على المقارنة بدواء وهمي في المرحلة الثالثة، لتقييم فعاليّة وسلامة ألبيليسيب الثلاثي السلبي المتقدم إمّا مع طفرة (nab-paclitaxel) بالاشتراك مع ناب-باكليّتاكسيل (BYL719) PI بدون طفرة في جين PTEN أو مع فقدان البروتين مماثل الفوسفاتاز والتنسين PIK3CA في جين	لدى المرضى المصابين بسرطان الثدي ا
Health conditions/problem studied: Specify	
Triple Negative Breast Neoplasms	



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Drug: alpelisib 300 mg orally once per day (QD) Other Name: BYL719 Drug: placebo 300 mg orally once per day (QD) Other Name: alpelisib matching placebo Drug: nab-paclitaxel 100 mg/m² as IV infusion on Days 1, 8 and 15 of a 28-day cycle Other Name: abraxane

Key inclusion and exclusion criteria: Inclusion criteria

Subject has histologically confirmed diagnosis of advanced (loco-regionally recurrent and not amenable to curative therapy, or metastatic (stage IV)) TNBC

Subject has either a measurable disease per RECIST 1.1 criteria or, if no measurable disease is present, then at least one predominantly lytic bone lesion or mixed lytic-blastic bone lesion with identifiable soft tissue component (that can be evaluated by CT/MRI) must be present Part B1: patients must have measurable disease

Subject has adequate tumor tissue to identify the PIK3CA mutation status (either carrying a mutation or without a mutation) and the PTEN loss status; both of which will determine whether the subject can be allocated to Part A - PIK3CA mutation regardless of PTEN status; or to Part B - PTEN loss without a PIK3CA mutation

Subject has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 Subject has received no more than one line of therapy for metastatic disease.

Subject has adequate bone marrow and organ function

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Age minimum

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Key inclusion and exclusion criteria: Exclusion criteria

Subject has received prior treatment with any PI3K, mTOR or AKT inhibitor

Subject has a known hypersensitivity to alpelisib, nab-paclitaxel or to any of their excipients

Subject has not recovered from all toxicities related to prior anticancer therapies to NCI CTCAE version 4.03 Grade ≤1; with the exception of alopecia

Subject has central nervous system (CNS) involvement

Subject with an established diagnosis of diabetes mellitus type I or uncontrolled type II based on Fasting Plasma Glucose and HbA1c Subject has impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of the study drugs (e.g., ulcerative diseases, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, or small bowel resection) based on investigator discretion

Subject has a history of acute pancreatitis within 1 year of screening or past medical history of chronic pancreatitis

Subject has currently documented pneumonitis/interstitial lung disease

Subject has a history of severe cutaneous reactions, such as Steven-Johnson Syndrome (SJS), erythema multiforme (EM), Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Syndrome (DRESS)

Subject with unresolved osteonecrosis of the jaw

Other protocol-defined inclusion/exclusion criteria apply.

Type of study

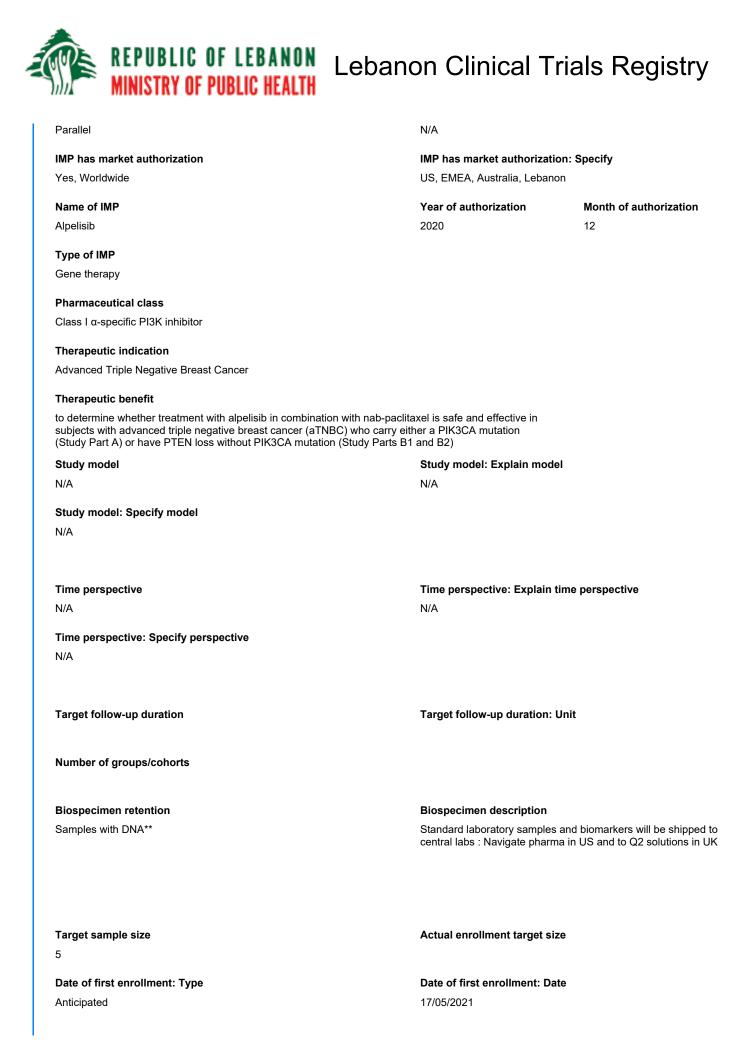
Interventional

Type of intervention	Type of intervention: Specify type
Pharmaceutical	N/A
Trial scope	Trial scope: Specify scope
-	
Safety	N/A
Study design: Allocation	Study design: Masking
Randomized controlled trial	Blinded (masking used)
Study design: Control	Study phase
Study design: Control	Study phase
Placebo	3
Study design: Purpose	Study design: Specify purpose
Treatment	N/A
noution	
Study design: Assignment	Study design: Specify assignment

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

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Date of study closure: Type	Date of study closure: Date
Anticipated	09/01/2026
Recruitment status Recruiting	Recruitment status: Specify
Date of completion	
24/08/2023	
IPD sharing statement plan	IPD sharing statement description
Yes	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://www.clinicaltrials.gov/ct2/show/study/NCT04251533?term=CBYL719	This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com
Admin comments	

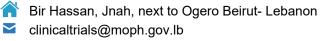
Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
Clinical trials. gov	NCT04251533	

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	Jawad Makarem	Al Chouf	Lebanon	03484288	Jawad.Makarem @awmedicalvilla ge.org	Ain Wazein Medical Village
Scientific	Hind Khairallah	Sinelfil	Lebanon	01512002# 271	Hind.khairallah@ fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Joseph Kattan	Ashrafieh	Lebanon	009613635 913	jkattan62@hotm ail.com	Hotel-Dieu de France
Public	Nagi El Saghir	Beirut	Lebanon	009613827 955	ns23@aub.edu.l b	American University of Beirut Medical Center

Centers/Hospitals Involved in the Study				
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval	
Ain Wazein Medical Village	Jawad Makarem	Hematology oncology	Approved	
Hotel-Dieu de France	Joseph Kattan	Hematology and Oncology	Approved	
American University of Beirut Medical Center	Nagi El Saghir	Hematology and Oncology	Approved	

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Ain w Zein Medical Village	14/01/2021	Hayat Kamaleddine	irb@awmedicalvillage.org	+961 (0) 5 509 001 ext 2014
Hotel Dieu de France	03/11/2020	Nancy Alam	nancy.alam@usj.edu.lb	+961 1 421 000 ext 2335
American University of Beirut Medical Center	03/08/2021	Fuad Ziyadeh	fz05@aub.edu.lb	+9611350000 ext 5445





Countries of Recruitment
Name
Lebanon
Australia
Austria
Brazil
Bulgaria
Colombia
Croatia
France
Germany
Hungary
India
Italy
Republic of Korea
Malaysia
Norway
Poland
Russian Federation
Slovakia
Spain
Switzerland
Taiwan
Turkey
United Kingdom
United States of America



Health Conditions or Problems Studied			
Condition Code Keyword			
Triple Negative Breast Neoplasms	Malignant neoplasm of breast (C50)	Triple Negative Breast Neoplasms	

Interventions		
Intervention	Description	Keyword
IMP administration , ICF, visit assessment and schedule	IMP administration , ICF, visit assessment and schedule	IMP administration , ICF, visit assessment and schedule

Primary Outcomes				
Name	Time Points	Measure		
Progression-free Survival (PFS) Per Investigator Assessment in Study part A	Once approximately 192 PFS events in Study Part A had been observed	up to 35 months		
Progression-free Survival (PFS) Per Investigator Assessment in Study part B2	Once approximately 192 PFS events in Study Part B2 had been observed	up to 22 months		
Overall Response Rate (ORR) based on local radiology assessments in subjects with measurable disease at baseline in study Part B1	Up to 6 months	Up to 6 months		

Key Secondary Outcomes				
Name	Time Points	Measure		
Overall Survival (OS) in Study Part A	Up to 66 months	Up to 66 months		
Overall Survival (OS) in Study Part B2	Up to 41 months	Up to 41 months		
Overall response rate (ORR) with confirmed response in Study Part A	Up to 35 months	Up to 35 months		
Overall response rate (ORR) with confirmed response in Study Part B2	Up to 22 months	Up to 22 months		
Clinical benefit rate (CBR) with confirmed response in Study Part A	Up to 35 months	Up to 35 months		
Clinical benefit rate (CBR) with confirmed response in Study Part B1	Up to 6 months	Up to 6 months		
Clinical benefit rate (CBR) with confirmed response in Study Part B2	Up to 22 months	Up to 22 months		
Time to response (TTR) in Study Part A	Up to 35 months	Up to 35 months		
Time to response (TTR) in Study Part B1	Up to 6 months	Up to 6 months		
Time to response (TTR) in Study Part B2	Up to 22 months	Up to 22 months		
Duration of Response (DOR) with confirmed response in Study Part A	Up to 35 months	Up to 35 months		

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Duration of Response (DOR) with confirmed response in Study Part B1	Up to 6 months	Up to 6 months
Duration of Response (DOR) with confirmed response in Study Part B2	Up to 22 months	Up to 22 months
Overall Survival (OS) in Study Part B1	Up to 6 months	Up to 6 months
Progression-free Survival (PFS) Per Investigator Assessment in Study part B1	Up to 6 months	Up to 6 months
Plasma concentrations of alpelisib - Part A	Up to 35 months	Up to 35 months
Plasma concentrations of alpelisib - Part B1	Up to 6 months	Up to 6 months
Plasma concentrations of alpelisib -Part B2	up to 22 months	up to 22 months
Plasma concentrations of paclitaxel - Part A	Up to 35 months	Up to 35 months
Plasma concentrations of paclitaxel - Part B1	up to 6 months	up to 6 months
Change from baseline in the global health status/Quality of life (QoL) scale score of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30- item Core Module (EORTC QLQ-C30) in study Part A	Up to 35 months	Up to 35 months
Change from baseline in the global health status/QoL scale score of the EORTC QLQ-C30 in study Part B2	Up to 22 months	Up to 22 months
Time to 10% definitive deterioration in the global health status/QOL scale score of the EORTC QLQ-C30 in study Part A	Up to 35 months	Up to 35 months
Time to 10% definitive deterioration in the global health status/QOL scale score of the EORTC QLQ-C30 in study Part B2	Up to 22 months	Up to 22 months
PFS based on local radiology assessments using RECIST 1.1 criteria for subjects by PIK3CA mutation status measured in baseline ctDNA in study Part A	Up to 35 months	Up to 35 months
PFS based on local radiology assessments using RECIST 1.1 criteria for subjects by PIK3CA mutation status measured in baseline ctDNA in study Part B2	Up to 22 months	Up to 22 months
Time to definitive deterioration of the Eastern Cooperative Oncology Group (ECOG) performance status (PS) from baseline in Study Part A	Up to 35 months	Up to 35 months
Time to definitive deterioration of the ECOG performance status from baseline in Study Part B2	Up to 22 months	Up to 22 months



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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