# REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

Study of Alpelisib (BYL719) in Combination With Trastuzumab and Pertuzumab as Maintenance Therapy in Patients With HER2 -positive Advanced Breast Cancer With a PIK3CA Mutation

20/08/2025 05:55:09

Novartis Pharmaceuticals       Novartis Pharmaceuticals         Date of registration in primary registry       Date of registration in national regulatory agency         13/09/2023       Acronym         Public title       Acronym         Study of Alpelisib (BYL719) in Combination With Trastuzumab and Pertuzumab as Maintenance Therapy in Patients With HER2- positive Advanced Breast Cancer With a PIK3CA Mutation       Acronym         Scientific title       Acronym         EPIK-B2: A Two Part, Phase III, Multicenter, Randomized (1:1), Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719) in Combination With Trastuzumab and Pertuzumab as Maintenance Therapy in Patients With HER2- positive Advanced Breast Cancer With a PIK3CA Mutation       EPIK-B2         Brief summary of the study: English Phase III study is to evaluate the efficacy and safety of alpelisib compared to alpelisib matching-placebo in combination with trastuzumab and pertuzumab and pertuzumab. Part 1 is the open-label, safety run-in part of the study, designed to confirm the recommended phase 3 dose (RP3D) dose of alpelisib in combination with trastuzumab and pertuzumab. Part 1, Part 2 will be initiated, which is the randomized, Phase III part of the study.       Site of R3D dose of alpelisib in combination with trastuzumab and pertuzumab. Part 1, Part 2 will be initiated, which is the randomized, Phase III part of the study.	Aain Information	
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	ان دواء أليبليسيب عندما يُضاف إلى تراستوزوماب ويرتوزوماب يساعد على الحدّ من نموّ خلايا سرطان HER2. "Pittic "الثدي لدى المرضى المصابين بسرطان الثدي المتقدّم إيجابي البروتين "هير	هدف هذه الدر اسة هو معرفة ما إذا ك

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REPUBLIC OF LEBANON Le

# Lebanon Clinical Trials Registry

Advanced HER2+Breast Cancer

### Interventions: Specify

Drug: Alpelisib Alpelisib - continuous once daily, in a 21-day cycle Other Name: BYL719

Drug: Alpelisib matching Placebo

Alpelisib matching placebo: continuous once daily, in a 21-day cycle

Drug: Trastuzumab Trastuzumab - Day 1 of Cycle 1, and on Day 1 (+/- 3 days) of every cycle thereafter

Drug: Pertuzumab Pertuzumab - Day 1 of Cycle 1, and on Day 1 (+/- 3 days) of every cycle thereafter

### Key inclusion and exclusion criteria: Inclusion criteria

- Participant has histologically-confirmed HER2-positive breast cancer that is advanced (loco-regionally not amenable to surgery or is metastatic).

- Participant has received pre-study induction therapy with up to and including a maximum of 6 cycles of a taxane (docetaxel, paclitaxel, or nabpaclitaxel), plus trastuzumab and pertuzumab. 4 or 5 cycles of induction therapy are permitted if discontinuation of taxane was due to taxane toxicity.

- Participant has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1

- Participant has adequate bone marrow and organ function

- Applies only to Part 2: Participant has a PIK3CA mutation(s) present in tumor tissue prior to enrollment, as determined by a Novartis designated central laboratory.

Key inclusion and exclusion criteria: Gender

Key inclusion and exclusion criteria: Specify gender

Both

18

Key inclusion and exclusion criteria: Age minimum

Key inclusion and exclusion criteria: Age maximum

# Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:

- Participant with inflammatory breast cancer at screening.

- Participant with evidence of disease progression during the pre-study induction therapy and prior to first dose of alpelisib (or alpelisib/alpelisib matching-placebo for Part 2)

- Participant with an established diagnosis of diabetes mellitus type I or uncontrolled type II based on fasting plasma glucose (FPG) and HbA1c.

- Participant has a known history of acute pancreatitis within 1 year of screening or past medical history of chronic pancreatitis
- Participant has clinically significant, uncontrolled heart disease and/or recent cardiac events
- Participant has a history of Steven-Johnson Syndrome (SJS), erythema multiforme (EM) or Toxic Epidermal Necrolysis (TEN).

- Participant has currently documented pneumonitis/interstitial lung disease

## Type of study

Interventional

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

# REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

Other	sequential	
IMP has market authorization	IMP has market authorization: S	pecify
Yes, Worldwide	USA, Europe	
Name of IMP	Year of authorization	Month of authorization
Alpelisib	2019	5
Type of IMP		
Gene therapy		
Pharmaceutical class		
phosphatidylinositol 3-kinase (PI3K) inhibitor		
Therapeutic indication		
Patients with HER2-positive Advanced Breast Cancer with a PIK3CA Mutation	n	
Therapeutic benefit		
Progression Free Survival		
Study model	Study model: Explain model	
N/A	N/A	
Study model: Specify model		
N/A		
Time perspective	Time perspective: Explain time	perspective
N/A	N/A	
Time perspective: Specify perspective N/A		
Target follow-up duration	Target follow-up duration: Unit	
Number of groups/cohorts		
Biospecimen retention	Biospecimen description	
Samples with DNA**	Samples will be shipped to Q2 sol	utions lab
8	Actual enrollment target size	
Date of first enrollment: Type	Date of first enrollment: Date	
Anticipated	28/12/2022	
Date of study closure: Type	Date of study closure: Date	



Anticipated	07/06/2023
Recruitment status	Recruitment status: Specify
Suspended	
Date of completion	
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 expert 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	This trial data is currently available according to the process described on www.clinicalstudydatarequest.com. https://www.clinicalstudydatarequest.com
https://clinicaltrials.gov/ct2/show/record/NCT04208178?term=CBYL719G123	301&draw=2&rank=1

Admin comments

# Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
Clinical trials.gov	NCT04208178	

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 753155	drfadi.trials@gm ail.com	Hammoud Hospital University Medical Center
Scientific	Hind Khairallah	Beirut	Lebanon	+961 1 512002 Ext. 271	hind.khairallah@f attal.com.lb	Khalil Fattal et Fils s.a.l
Public	Marwan Ghosn	Beirut	Lebanon	+961 3 226842	marwan.ghosn@ usj.edu.lb	Hotel Dieu de France Hospital
Public	Hampig Raphael Kourie	Dora	Lebanon	+961 3 321899	hampig.kourie@ usj.edu.lb	Hopital Saint Joseph

Centers/Hospitals Involved in the Study				
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval	
Hammoud Hospital University Medical Center	Fadi Farhat	Hematology Oncology	Approved	
Hotel Dieu de France	Marwan Ghosn	Hematology Oncology	Approved	
Hopital Saint Joseph	Hampig Raphael Kourie	Oncology	Approved	

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	30/06/2021	Ibrahim Omeis	iomeis@hammoudhospital.org	+961 (0) 7 723111 ext 1222/1223
Hotel Dieu de France	29/09/2021	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Psychiatric Hospital of the Cross	08/09/2022	Christiane Abi Elias	irghpc@gmail.com	+961 (0) 3 953794



# **Countries of Recruitment**

Name
Belgium
China
France
Spain
United States of America
Lebanon

Health Conditions or Problems Studied			
Condition	Code Keyword		
Advanced HER2+Breast Cancer	Malignant neoplasm of breast (C50)	Advanced HER2+Breast Cancer	

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	
Part 1	6 weeks	Incidence of dose limiting toxicities (DLTs) for each dose level	
Part 2	Up to approximately 38 months	Progression Free Survival (PFS)	

# REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH Lebanon Clinical Trials Registry

Key Secondary Outcomes			
Name	Time Points	Measure	
Part 1	Day 8 of Cycle 1 and then Day 1 of Cycle 2, Cycle 4, Cycle 6 and Cycle 10 (Each cycle = 21 days)	Summary statistics of alpelisib concentrations by timepoint and dose level	
Part 2	Up to approximately 70 months	Overall survival (OS)	
Part 2	Day 8 of Cycle 1 and then Day 1 of Cycle 2, Cycle 4, Cycle 6 and Cycle 10 (Each cycle = 21 days)	Summary statistics of alpelisib concentrations by timepoint and dose level	
Part 2	Up to approximately 38 months	Overall response rate (ORR) with confirmed response	
Part 2	Up to approximately 38 months	Clinical Benefit Rate (CBR) with confirmed response	
Part 2	Up to approximately 38 months	Time to response (TTR) based on local radiology assessments	
Part 2	Up to approximately 38 months	Duration of response (DOR) with confirmed response	
Part 2	Baseline, approximately 38 months	Change in Functional Assessment of Cancer Therapy - Breast (FACT-B) treatment outcomes index (TOI) from baseline	
Part 2	Up to approximately 38 months	Time to deterioration in FACT-B TOI (defined as a $\ge 5$ point decrease from baseline)	
Part 2	Up to approximately 38 months	PFS based on local radiology assessments	
Part 2	Baseline, up to approximately 38 months	Time to definitive deterioration of Eastern Cooperative Group of Oncology Group (ECOG) performance status	



# 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