Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	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
Protocole ID	EPIK-B2
ClinicalTrials.gov ID	NCT04208178
Type(s) de cancer	Sein
Phase	Phase III
Médicament	Alpelisib en association avec trastuzumab et pertuzumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
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Statut	Fermé
But étude	The purpose of this two part multicenter, randomized, double-blind, placebo-controlled, Phase III study is to evaluate the efficacy and safety of alpelisib compared to alpelisib matching-placebo in combination with trastuzumab and pertuzumab as maintenance treatment of patients with HER2-positive advanced breast cancer whose tumor harbors a PIK3CA mutation following induction therapy with a taxane in combination with trastuzumab 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. Following Part 1, Part 2 will be initiated, which is the randomized, Phase III part of the study.
Critères d'éligibilité	• 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 8 cycles of a taxane (docetaxel, paclitaxel, or nab-paclitaxel), plus trastuzumab and pertuzumab. 4 or 5 cycles of induction therapy are permitted if discontinuation of taxane was due to taxane toxicity. Of note, participants enrolled in Part 1 of this study received 4-6 cycles of pre-study induction therapy. • 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 prior to enrollment, locally confirmed per test listed in protocol or as determined by a Novartis designated central laboratory.
Critères d'exclusion	• 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

Other protocol-defined Inclusion/Exclusion may apply.