Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	A Phase 3, Randomized, Double-blind Study of Encorafenib and Binimetinib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab in Participants With BRAF V600E/K Mutation-Positive Metastatic OR Unresectable Locally Advanced Melanoma
Protocole ID	STARBOARD (KEYNOTE-B80)
ClinicalTrials.gov ID	NCT04657991
Type(s) de cancer	Mélanome
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Encorafenib avec binimetinib + pembrolizumab
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
Investigateur principal	Dr José Luiz Miranda Guimaraes
Coordonnateur	Sabrina Côté 418-541-1000 poste 3065
Statut	Fermé
Date d'activation	11-11-2022
But étude	The purpose of this study is to learn about the effects of three study medicines (encorafenib, binimetinib, and pembrolizumab) given together for the treatment of melanoma that: • is advanced or metastatic (spread to other parts of the body); • has a certain type of abnormal gene called "BRAF"; and • has not received prior treatment. All participants in this study will receive pembrolizumab at the study clinic once every 3 weeks as an intravenous (IV) infusion (given directly into a vein). In addition, half of the participants will take encorafenib and binimetinib orally (by mouth) at home every day. Participants may receive pembrolizumab for up to two years. Those participants taking encorafenib and binimetinib can continue until their melanoma is no longer responding. The study team will monitor how each participant is doing with the study treatment during regular visits at the study clinic.
Critères d'éligibilité	• Male or female participants ≥ 18 years at the time of informed consent. • Participants who are willing and able to comply with all scheduled visits, treatment plan, laboratory tests, lifestyle considerations, and other study procedures. • Histologically confirmed unresectable (Stage IIIB, IIIC, or IIID) or metastatic (Stage IV) cutaneous melanoma, according to the AJCC 8th edition. • Presence of at least 1 measurable lesion as detected by radiological and/or photographic methods according to RECIST v1.1. • ECOG performance status 0 or 1. • Documented evidence of a BRAF V600E or V600K mutation in melanoma tumor tissue as previously determined by either PCR or NGS-based local laboratory assay (eg, US FDA-approved test, CE-marked [European conformity] in vitro diagnostic in EU countries, or equivalent), obtained during the course of normal clinical care, in a CLIA- or similarly certified laboratory.

	• Submission of adequate tumor tissue (archival or newly obtained; block or slides to the sponsor central laboratory(ies) during the screening period and prior to enrollment (SLI)/randomization (Phase 3). • Have not received prior first-line systemic therapy for metastatic or unresectable locally advanced melanoma. • Adequate bone marrow function, hepatic and renal function. • Capable of giving signed informed consent.
Critères d'exclusion	• Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study. • Mucosal or ocular melanoma. • Diagnosis of immunodeficiency or an active autoimmune disease that required systemic treatment in the past 2 years (ie, with use of disease modifying agents, corticosteroids, or immunosuppressive drugs). • Clinically significant multiple or severe drug allergies, intolerance to topical corticosteroids, or severe post-treatment hypersensitivity reactions (including, but not limited to, erythema multiforme major, linear IgA dermatosis, toxic epidermal necrolysis, and exfoliative dermatitis). • Unable to swallow, retain, and absorb oral medications. • Impairment of GI function or disease which may significantly alter the absorption of oral study intervention (eg, uncontrolled nausea, vomiting or diarrhea, malabsorption syndrome, including malabsorption syndrome secondary to prior GI surgery). • Clinically significant cardiovascular diseases, • History of thromboembolic or cerebrovascular events ≤ 12 weeks prior to enrollment (SLI)/randomization (Phase 3). Examples include transient ischemic attacks, cerebrovascular accidents, hemodynamically significant (ie, massive or sub-massive) deep vein thrombosis or pulmonary emboli. • History or current evidence of RVO or current risk factors for RVO (eg, uncontrolled glaucoma or ocular hypertension, history of hyperviscosity or hypercoagulability syndromes) • Concurrent neuromuscular disorder that is associated with the potential of elevated CK (eg, inflammatory myopathies, muscular dystrophy, amyotrophic lateral sclerosis, spinal muscular atrophy). • Current noninfectious pneumonitis or history of noninfectious pneumonitis requiring steroids, or history of radiation pnuemonitis • Evidence of HBV or HCV infection. • Known history of a positive test for HIV or known AIDS. • Any active infection requiring systemic therapeutic treatment within 2 weeks prior to enrollment (SLI)/ randomization (Phase 3). • Participants with prior or current symptomatic brain metastasis, leptomeningeal disease or other active CNS metastases. • Concurrent or previous other malignancy within 2 years of study entry, except curatively treated basal or squamous cell skin cancer, prostate intraepithelial neoplasm, carcinoma in-situ of the cervix, Bowen's disease and Gleason ≤ 6 prostate cancer. Participants with a history of other curatively treated cancers must be reviewed with the sponsor or designee prior to entering the study. • Participants who previously received and subsequently discontinued encorafenib and/or binimetinib and/or anti-PD-1/-L1 due to severe toxicity. • For participants in the SLI only: Current use or anticipated need for food or drugs that are known moderate or strong CYP3A4 inhibitors during screening and through the DLT-evaluation period • Participant has not recovered to Grade ≤ 1 from toxic effects of prior therapy and/or complications from prior surgical intervention before enrollment (SLI)/ randomization (Phase 3). • Receipt of protocol defined medications or treatments outside of required intervals before enrollment (SLI)/randomization (Phase 3): • Previous administration with an investigational drug ≤ 6 months prior to enrollment (SLI)/randomization (Phase 3). • Known sensitivity or contraindication to any component of study intervention (encorafenib, binimetinib and pembrolizumab), or their excipients. • Pregnant, confirmed by a positive β-hCG laboratory test result, or is breastfeeding (lactating). • Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.