Essai Clinique

Généré le 17 mai 2025 à partir de

Titre	A phase 1A/B open-label master study of PF-07799544 as a single-agent and in combination with other targeted agents in participants with advanced solid tumors
Protocole ID	C4901001
ClinicalTrials.gov ID	NCT05538130
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Type étude	Clinique
Médicament	PF-07799544
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Olivier Dumas
Coordonnateur	Geneviève Rochette 418-525-4444 poste 67540
Statut	Actif en recrutement
Date d'activation	10-07-2023
But étude	The purpose of this clinical trial is to learn the safety and effects of the study medicine (PF-07799544) administered as a single agent and in combination with other study medications in people with solid tumors. This study is seeking participants who have an advanced solid tumor for which the available treatments are no longer effective in controlling their cancer. All participants in this study will receive PF-07799544. PF-07799544 comes as a tablet to take by mouth daily (initially 2 times per day, but this could change to once daily or another frequency). Depending on the part of the study, participants may also receive another study medicine. • In the first part of the study, people with melanoma or other solid tumors may also receive encorafenib. Encorafenib comes as a capsule and is taken once per day. • In the second part of the study, people with melanoma with a certain type of abnormal gene called "BRAF" will receive PF-07799544 with other study medicines (for example, PF-07284890 or PF-07799933). Participants may receive the study medicines for about 2 years. The study team will monitor how each participant is doing with the study treatment during regular visits at the study clinic.
Critères d'éligibilité	• Diagnosis of advanced/metastatic solid tumor including primary brain tumor for monotherapy phase 1a dose escalation • Disease progressed during/following last prior treatment and no satisfactory alternative treatment options for monotherapy phase 1a dose escalation • For Substudy A and B, histological or cytological diagnosis of advanced/metastatic melanoma • For Substudy A and B, measurable disease by RECIST version 1.1 • For Substudy A, evidence of a BRAF V600 mutation in tumor tissue and/or blood • For Substudy B, evidence of a BRAF V600 mutation or BRAF Class II alteration in tumor tissue and/or blood

Critères d'exclusion	• Brain metastasis larger than 4 cm • Systemic anti-cancer therapy or small molecule therapeutics ongoing at the start of study treatment. • For participants who may get binimetinib on study, history or current evidence of retinal vein occlusion (RVO) or concurrent neuromuscular disorder associated with elevated creatine kinase (CK)