Essai Clinique

Généré le 15 mai 2024 à partir de

Titre	Étude de phase I/II sur le BMS-986340 administré en monothérapie et en association avec le nivolumab à des participants atteints de tumeurs solides à un stade avancé
Protocole ID	CA052-002
ClinicalTrials.gov ID	NCT04895709
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	BMS-986340 en monothérapie ou en association avec le nivolumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Rahima Jamal
Coordonnateur	Adeline Hamon 514-890-8000 poste 30737
Statut	Actif en recrutement
But étude	The purpose of this study is to assess the safety, tolerability, and recommended dose(s) of BMS-986340 as monotherapy and in combination with nivolumab in participants with advanced solid tumors. This study is a first-in-human (FIH) study of BMS-986340 in participants with advanced solid tumors.
Critères d'éligibilité	• Fresh pre-treatment and on-treatment tumor biopsy must be provided for biomarker analysis • Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and at least 1 lesion accessible for biopsy • Eastern Cooperative Oncology Group Performance Status of 0 or 1 • Radiographically documented progressive disease on or after the most recent therapy • Received standard-of-care therapies, including an available programmed death (ligand)-1 inhibitor known to be effective in the tumor type for which they are being evaluated • Parts 1A, 1B, and 2A: Advanced or metastatic non-small cell lung cancer, squamous cell carcinoma of head and neck, microsatellite stable colorectal cancer, gastric/ gastroesophageal junction adenocarcinoma, or cervical cancer, and have received, be refractory to, not be a candidate for, or be intolerant of existing therapies known to provide clinical benefit for the condition of the participant
Critères d'exclusion	• Women who are pregnant or breastfeeding • Primary central nervous system (CNS) malignancy • Untreated CNS metastases • Leptomeningeal metastases • Concurrent malignancy requiring treatment or history of prior malignancy active within 2 years prior to the first dose of study treatment • Active, known, or suspected autoimmune disease • Condition requiring systemic treatment with either corticosteroids within 14 days or other immunosuppressive medications within 30 days of the first dose of study treatment • Prior organ or tissue allograft • Uncontrolled or significant cardiovascular disease • Major surgery within 4 weeks of study drug administration

- History of or with active interstitial lung disease or pulmonary fibrosis

Other protocol-defined inclusion/exclusion criteria apply