Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	A Phase 3, Multinational, Randomized, Open-Label, Three Parallel-Arm Study of PF-06801591, an Anti-PD-1 Antibody, in Combination With Bacillus Calmette-Guerin (BCG Induction With or Without BCG Maintenance) Versus BCG (Induction and Maintenance) in Participants With High-Risk, BCG-Naïve Non-Muscle Invasive Bladder Cancer
Protocole ID	CREST (B8011006)
ClinicalTrials.gov ID	NCT04165317
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Clinique
Médicament	Sasanlimab avec BCG
Institution	CIUSSS DU SAGUENAY – LAC-SAINT-JEAN H HOPITAL DE CHICOUTIMI 305, rue Saint-Vallier G7H 5H6 , Chicoutimi, QC
Ville	
Investigateur principal	Dr Jean-Benoit Paradis
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Statut	Actif en recrutement
But étude	CREST: Combination of sasanlimab and alternative BCG Regimens to Evaluate outcomes with Subcutaneous anti-PD-1 Treatment Phase 3 Design with 3 study Arms (A, B and C). Arms A and B consists of two study drugs, PF-06801591 plus BCG. Arm C consists of one study drug, BCG. The study is designed to demonstrate that PF-06801591 plus Bacillus Calmette Guerin (BCG) (induction and maintenance periods) is superior to BCG alone (induction and maintenance periods) in prolonging event free survival (EFS) in participants with high-risk naïve non-muscle invasive bladder cancer (NMIBC) and to demonstrate that PF-06801591 plus BCG (induction period only) is superior to BCG alone (induction and maintenance periods) in prolonging EFS in participants with high-risk NMIBC.
Critères d'éligibilité	• Histological confirmed diagnosis of high risk non-muscle invasive transitional cell carcinoma (TCC) of the urothelium of the urinary bladder (tumors of mixed transitional/non-transitional cell histology are allowed, but TCC must be the predominant histology) • Complete resection of all Ta/T1 papillary disease (including participants with concurrent CIS), with most recent TURBT occurring within 12 weeks prior to randomization. A second TURBT must have been performed if indicated according to the current locally applicable guidelines, ie, American Urological Association, European Association of Urology
Critères d'exclusion	• Evidence of muscle-invasive, locally advanced or metastatic urothelial cancer or concurrent extravesical, non-muscle invasive TCC of the urothelium • Intravesical BCG therapy within 2 years prior to randomization. Prior intravesical chemotherapy for NMIBC is allowed • Prior immunotherapy with anti PD-1, anti PD-L1, anti PD-L2, or anti cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody • Prior treatment with immunostimulatory agents including interleukin (IL)-2, IL-15, interferon (INF) • Prior radiation therapy to the bladder