Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	An Open-label, Randomised, Multicentre, Phase III Study of Irinotecan Liposome Injection, Oxaliplatin, 5-fluorouracil/Leucovorin Versus Nab-paclitaxel Plus Gemcitabine in Subjects Who Have Not Previously Received Chemotherapy for Metastatic Adenocarcinoma of the Pancreas
Protocole ID	NAPOLI 3
ClinicalTrials.gov ID	NCT04083235
Type(s) de cancer	Pancréas
Phase	Phase III
Stade	Métastatique
Type étude	Clinique
Médicament	Injection d'irinotécan liposomal, oxaliplatine, 5-fluorouracil/leucovorin versus nab-paclitaxel + gemcitabine
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But étude	The purpose of this study is to look at the efficacy and safety of Irinotecan liposome injection in combination with other approved drugs used for cancer therapy, namely 5 fluorouracil/leucovorin (5FU/LV) plus oxaliplatin compared to nab-paclitaxel + gemcitabine treatment in improving the overall survival of patients not previously treated for metastatic pancreatic cancer.
Critères d'éligibilité	• Histological or cytologically confirmed adenocarcinoma of the pancreas that has not been previously treated in the metastatic setting. • Initial diagnosis of metastatic disease must have occurred ≤6 weeks prior to screening. • Subject has one or more metastatic tumours measurable by computed tomography (CT) scan (or magnetic resonance imaging (MRI), if the subject is allergic to CT contrast media) according to RECIST Version 1.1 criteria. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Subject has adequate biological parameters as demonstrated by the following blood counts:(a) Absolute neutrophil count (ANC) ≥2000/mm3 without the use of hemopoietic growth factors within the last 7 days prior to randomisation (b) Platelet count ≥100,000/mm3 (c) Haemoglobin (Hgb) ≥9 g/dL obtained ≤14 days prior to randomisation. • Adequate hepatic function as evidenced by: (a) Serum total bilirubin ≤1.5x ULN (biliary drainage is allowed for biliary obstruction), and (b) Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤2.5x upper limit of normal (ULN) (≤5x ULN is acceptable if liver metastases are present). • Adequate renal function as evidenced by creatinine clearance ≥30 mL/min. • Adequate coagulation studies (obtained ≤14 days prior to randomisation) as demonstrated by prothrombin time and partial thromboplastin time within normal limits (≤1.5xULN).

Critères d'exclusion	• Prior treatment of pancreatic cancer in the metastatic setting with surgery, radiotherapy, chemotherapy or investigational therapy • Prior treatment of pancreatic adenocarcinoma with chemotherapy in the adjuvant setting, except those where at least 12 months have elapsed since completion of the last dose and no persistent treatment-related toxicities are present. • Subject has only localised advanced disease. • Documented serum albumin <3 g/dL • Known history of central nervous system (CNS) metastases. • Clinically significant gastrointestinal disorder • History of any second malignancy in the last 2 years • Concurrent illnesses that would be a relative contraindication to trial participation • Use of strong inhibitors or inducers of CYP3A, CYP2C8 and UGT1A1 • Neuroendocrine (carcinoid, islet cell) or acinar pancreatic carcinoma • Known low or absent dihydropyrimidine dehydrogenase (DPD) activity