

A Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Anti-tumour Activity of IPN01203 in Adults With Locally Advanced or Metastatic Solid Tumours Exposed to Immune Checkpoint Inhibitor Therapies

NCT07213830

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Ipsen
Enrollment	102 participants

Key Eligibility Criteria

Inclusion (8)

- Participant must be ≥18 years of age, at the time of signing the informed consent.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- Measurable disease per RECIST version 1.1 (at least one lesion that is measurable by RECIST 1.1. Tumour lesions in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions after radiation) and documented locally advanced or metastatic disease with CT and/or MRI.
- All acute, clinically significant (CS) treatment-related AEs from a prior therapy resolved to Grade 1 or lower prior to study entry. Participants with chronic toxicities such as Grade 2 neuropathy or alopecia can be included.
- Have a life expectancy for disease-related mortality, as evaluated by the investigator.

... and 3 more (see full listing online)

Exclusion (22)

- Have untreated or active primary brain tumour, Central Nervous System (CNS) metastases, leptomeningeal disease, or spinal cord compression.
- Experienced severe, life-threatening immune-mediated AEs, or infusion-related reactions such as those that lead to permanent discontinuation while on treatment with prior anticancer therapy such as immune checkpoint inhibitor therapy.
- History of known autoimmune disease
- History of stroke or significant cerebrovascular disease, encephalitis, meningitis, organic brain disease (e.g., Parkinson's disease) or uncontrolled seizures in the year prior to first dose of study drug.
- Left ventricular ejection fraction <45%

... and 17 more (see full listing online)

Locations (11 total)

Dana-Farber Cancer Institute, Boston, Massachusetts, United States
START MidWest PI Sharma, Grand Rapids, Michigan, United States
Sarah Cannon Research Institute PI McKean Nashville, TN, USA, Nashville, Tennessee, United States
... and 8 more locations

<https://clinicaltrials.gov/study/NCT07213830>

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