

A Study to Assess a New Medicine Called IPN01195 When Administered Alone in Adults With Advanced Solid Tumours

NCT06833008

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Ipsen
Enrollment	85 participants

Key Eligibility Criteria

Inclusion (9)

- Participants must be ≥18 years of age or the country's legal age of majority if the legal age is more than 18 years at the time of signing the informed consent.
- Participants with histologically confirmed metastatic solid tumour for whom no suitable alternative standard therapy exists.
- Participants must bear tumours harbouring selected classes of genetic alterations of MAPK pathway based on an analytically validated assay performed by an accredited laboratory.
- Part A: Participants must consent to the use of archival tumour tissue or, if not available, collection of fresh tumour biopsy at screening, for central confirmation of mutation status.
- Part B: Participants must consent to the use of archival tumour tissue or, if not available, collection of fresh tumour biopsy at screening, for MAPK genomic testing to confirm eligibility.

... and 4 more (see full listing online)

Exclusion (20)

- Gastrointestinal conditions that could impair absorption of IPN01195 (specific cases e.g. remote history of gastrointestinal surgery, may be enrolled after discussion with the medical monitor)
- Any evidence of severe active infection or inflammatory condition.
- Non-adequate cardiac function
- Known psychiatric or substance abuse disorder, or any other cognitive disorder per the opinion of the investigator that would interfere with the participant's ability to cooperate with the requirements of the study.
- Underlying medical conditions that, in the investigator's or sponsor's opinion, will obscure the interpretation of toxicity determination or AEs.

... and 15 more (see full listing online)

Locations (13 total)

START Mid-West, Grand Rapids, Michigan, United States
Sarah Cannon Research Institute (SCRI) - Nashville, Nashville, Tennessee, United States
Mary Crowley Cancer Research Centers - Medical City Hospital - Dallas, Dallas, Texas, United States
... and 10 more locations