

A Phase 1 First-In-Human Study of the Anti-CD73 IPH5301 Alone or in Combination With Chemotherapy and Trastuzumab in Patients With Advanced Solid Tumors

NCT05143970

Status	RECRUITING
Phase	Phase 1
Sponsor	Institut Paoli-Calmettes
Enrollment	27 participants

Key Eligibility Criteria

Inclusion (15)

- Patients with incurable advanced and/or metastatic cancer.
 - Patients with any of the following cancers:
 - In dose escalation: carcinoma of the breast, stomach, esophagus, pancreas, endometrium, ovary or lung.
 - In cohort expansion : carcinoma of the breast that expresses HER2. Eligibility is based on HER2 expression as determined locally. HER2-positive is defined by IHC 3+ or gene amplification by in situ hybridization and HER2-low is defined by IHC 1+ or 2+ and no gene amplification by in situ hybridization.
 - Prior treatment with at least one prior systemic therapy in the advanced metastatic setting
- ... and 10 more (see full listing online)

Exclusion (21)

- Prior treatment with other monoclonal antibodies or small mol-ecules targeting CD73 or the adenosine pathway.
 - Patients with known spinal cord compression.
 - Patients with grade 2 or higher peripheral neuropathy.
 - Symptomatic, untreated, or actively progressing central nerv-ous system (CNS) metastases. Patients with suspected CNS involvement at screening should have an magnetic resonance imaging (MRI) (preferred) or computed tomography (CT) each preferably with IV contrast of the brain prior to study entry to rule them out. Asymptomatic patients with treated CNS lesions are eligible, provided that defined criteria are met
 - Known allergic reactions attributed to compounds of similar product.
- ... and 16 more (see full listing online)

Locations (1 total)

Institut Paoli Calmettes, Marseille, France