Oral Pooled Fecal Microbiotherapy (MaaT033) Concomitant to Cemiplimab Versus Best Investigator's Choice in Patients With Resistance to Treatment Due to Antibiotics Uptake With Advanced Non-small Cell Lung Cancer

NCT07001618

Status	RECRUITING
Phase	Phase 2
Sponsor	Gustave Roussy, Cancer Campus, Grand Paris
Enrollment	162 participants

Key Eligibility Criteria

Inclusion (18)

- Participants who are at least 18 years of age on the day of signing informed consent,
- All participants must understand spoken and written national language,
- Histologically confirmed diagnosis of NSCLC (adenocarcinoma versus squamous cell carcinoma versus others)
- Have metastatic or unresectable NSCLC and considered by their physician to be indicated for a new line of immunotherapy.
- Have an Eastern Cooperative Oncology Group performance status (ECOG-PS) of 0 to 2. Evaluation of ECOG-PS is to be performed within 7 days prior to the date of treatment allocation.

... and 13 more (see full listing online)

Exclusion (16)

- Immunodeficiency or systemic steroid therapy equivalent to prednisolone \>10mg/day or equivalent within 7 days prior to the first dose of trial treatment.
- Active ongoing infection requiring ATB treatment.
- Has a known additional malignancy that is progressing or has required active treatment within the past 3 years prior to enrollment. Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (e.g. breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy are not excluded.
- Has received prior radiotherapy within 2 weeks of start of study treatment. Participants must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis. A 1-week washout is permitted for palliative radiation (d2 weeks of radiotherapy) to non-central nervous system (CNS) disease.
- Has received a live vaccine within 30 days prior to the first dose of study drug. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacillus Calmette-Guérin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (eg, FluMist®) are live attenuated vaccines and are not allowed.

... and 11 more (see full listing online)

Locations (6 total)

Centre Georges François Leclerc, Dijon, France
CHU Grenoble, Grenoble, France
Hôpital Bichat - Claude Bernard, Paris, France
... and 3 more locations