*GDFATHER*

# First-in-Human Study of the GDF-15 Neutralizing Antibody CTL-002 in Patients With Advanced Cancer (GDFATHER)

**NCT-Nummer:**
NCT04725474

**Studienbeginn:**
Dezember 2020

**Letztes Update:**
04.05.2021

**Wirkstoff:**
CTL-002
**Geschlecht:**
Alle

**Altersgruppe:**
Erwachsene (18+)

**Phase:**
Phase 1

**Sponsor:**
CatalYm GmbH

**Collaborator:**
-

## Studien-Informationen

**Brief Summary:**

Part A will be a dose escalation study of IV CTL002 (a monoclonal antibody neutralizing GDF-15) as monotherapy and in combination with an approved checkpoint inhibitor (CPI) in patients with advanced solid tumors. Part B will be a cohort expansion into up to five solid

tumor indications.

## Ein-/Ausschlusskriterien

Main **Inclusion Criteria:**

- Signed and dated informed consent, and able to comply with the study procedures and any locally required authorization.

- Male or female aged ≥ 18 years.

- Relapsed/refractory patients with histologically or cytologically confirmed diagnosis of advanced-stage or recurrent cancer

- Progressed on/relapsed after at least one prior anti-PD-1/PD-L1 treatment

- Biopsy-accessible tumor lesions and willing to undergo triple sequential tumor biopsy (Part A).

- At least 1 radiologically measurable lesion per RECIST V1.1/imRECIST (Part B).

- Eastern Cooperative Oncology Group (ECOG) performance status 0-1.

- Life expectancy > 3 months as assessed by the Investigator.

- Adequate organ function (bone marrow, hepatic, renal function and coagulation).

Main **Exclusion Criteria:**

- Pregnant or breastfeeding.

- Any tumor-directed therapy within 21 days before study treatment.

- Treatment with investigational agent within 21 days before study treatment.

- Radiotherapy within 14 days before study treatment.

- Pre-existing arrhythmia, uncontrolled angina pectoris, uncontrolled heart failure (NYHA II-IV), any myocardial infarction/coronary event, CNS-ischemic event and any thromboembolic event at any time < 6 months prior to Screening.

- Left ventricular ejection fraction (LVEF) < 50% measured by echocardiogram or MUGA.

- QTcF > 450 ms for men or > 470 ms for women.

- Any active autoimmune requiring systemic immunosuppressive treatments. .

- Any history of non-infectious pneumonitis < 6 months prior to Screening.

- Any active inflammatory bowel disease such as Crohn's disease or ulcerative colitis

which are generally excluded or active autoimmunthyroiditis present < 6 months prior

to Screening.

- History of CNS disease such as stroke, seizure, encephalitis, or multiple sclerosis (<

6 months prior to Screening).

## Studien-Rationale

**Primary outcome:**

1. Adverse Events (Parts A & B) (Time Frame - min. 2 months):
*Incidence of treatment emergent adverse events in monotherapy and/or combination therapy*

2. Determination of DLT and MTD (Part A) (Time Frame - 28 days):
*Assessment of toxicities in monotherapy and/or combination therapy per dose level*

3. Evaluation of clinical efficacy according RECIST (Part B) (Time Frame - min. 6 weeks):
*RECIST is measured every 6-8 weeks treatment*

**Secondary outcome:**

1. Cmax following the first dose of CTL-002 (Part A & B) (Time Frame - 1 day):
*PK parameter from serum CTL-002 levels*

2. AUC following the first dose of CTL-002 (Part A & B) (Time Frame - 14 days):
*PK parameter from serum CTL-002 levels*

3. Half-life of CTL-002 (Part A & B) (Time Frame - min. 6 weeks):
*PK parameter from serum CTL-002 levels*

4. Evaluation of treatment-emergent cytokine/chemokine concentrations (including TNF-a, IFN-g, IL-2, CXCL-9 and CXCL-10) (Part A & B) (Time Frame - min. 6 weeks):
*Measurement of concentration in peripheral blood*

5. Evaluation of clinical efficacy according RECIST (Part A) (Time Frame - min. 6 weeks):
*RECIST is measured every 6-8 weeks during treatment*

6. Evaluation of appetite (Time Frame - min. 6 weeks):
*Assessment of appetite via quality of life questionnaire*

7. Assessment of Body-Mass-Index (BMI) (kg/m2) (Time Frame - min. 6 weeks):
*Calculation of BMI in kg/m2 by combining measurement of body weight in kg and body height in*

*cm*

8. Assessment of lumbar vertebra skeletal muscle index (L3SMI) (cm2/m2) (Time Frame - min. 6 weeks):
*Combining measurement of L3 vertebra skeletal muscle mass via computed tomography (CT) in cm2 and patient height (squared) in m2*

## Studien-Arme

- Experimental: Part A: CTL-002 Monotherapy + Checkpoint Inhibitor Combination Dose Escalation
  *Up to five dose levels with CTL-002 administered as IV monotherapy and in combination with an checkpoint inhibitor*
- Experimental: Part B: CTL-002 Monotherapy + Checkpoint Inhibitor combination
  *Up to 2 dose levels with CTL-002 in Part B (expansion)*

## Geprüfte Regime

- CTL-002:
  *monoclonal antibody*

## Studienleiter

**Eugen Leo, MD, PhD, MBA**
Study Director
*CatylYm GmbH*

## Kontakt

**Eugen Leo, MD, PhD, MBA / CMO**
***Kontakt:***
Phone: +49 89 200066440
E-Mail: eugen.leo@catalym.com

**Petra Fettes, PhD**
***Kontakt:***
Phone: +49 89 200066440
E-Mail: petra.fettes@catalym.com

## Studienlocations (3 von 6)

**Universitätsklinikum Essen, Westdeutsches Tumorzentrum, Innere Klinik und Poliklinik**
45147 Essen

(Nordrhein-Westfalen)
Germany

**Status: Noch nicht rekrutierend**

**Universitätsklinikum Würzburg, Comprehensive Cancer Center**
97078 Würzburg
(Bayern)
Germany

**Status: Rekrutierend**

**Hospital Universitari Vall d'Hebron, Institute of Oncology**
08035 Barcelona
Spain

**Status: Rekrutierend**

**START Madrid, Hospital Universitario HM Sanchinarro**
28050 Madrid
Spain

**Status: Rekrutierend**

**Clinica Universidad de Navarra, Unidad Central de Ensayos Clinicos**
31008 Pamplona
Spain

**Status: Rekrutierend**

**University Hospital Zurich, Department of Dermatology**
9091 Zurich
Switzerland

**Status: Rekrutierend**

*Quelle: ClinicalTrials.gov*