A phase II study of durvalumab (MEDI4736) plus tremelimumab for the treatment of patients with progressive, refractory advanced thyroid carcinoma (DUTHY study)

STUDY DESIGN

- **Screening (days -28 to -2)**
- **Basal Visit (days -3 to day 0)**
- **Cycles (28 days)**
  - Durvalumab + Tremelimumab
  - Durvalumab Monotherapy

- **EoT Visit**
- **Follow-up**

- **Progression Unacceptable toxicity**

**Inclusion**
- Durvalumab 1500 mg
- Tremelimumab 75 mg

**Durvalumab + Tremelimumab Treatment**
- 4 cycles (28 days)

**Durvalumab Monotherapy**
- Cycles (28 days)

**Follow-up**
- Progression Unacceptable toxicity
- EoT
- Follow-up every 12 weeks to determine SG

**Basal Visit**
- C1D1
- C1D15
- C2D1
- C2D15
- C3D1
- C3D15
- C4D1
- C5D1
- C6D1
- CxD1

**Studying**
- PI: Dr. Jaume Capdevila
Cohort 1 and 2 patients will be included according to a two-stage Simon design, with the inclusion of 17 patients in phase I and 19 patients in phase II, for a total of 36 patients / cohort.

- If ≥ 5 patients of the 17 patients included in the first phase do not progress or have unacceptable toxicity at 6 months, the second phase will begin, including 19 more patients.

- Cohort 3 patients will be included in a single phase, up to a total of 12 patients.