A randomized multicentric phase II trial of trastuzumab vs trastuzumab + avelumab in HER2+ ER- patients at high risk of relapse after neo-adjuvant treatment: the TRAVEL study

Keywords: Trastuzumab, Avelumab, Residual disease, TILs

# Background

- Patients with residual disease after neoadjuvant therapy for HER2+/ER- breast cancer have worse prognosis
- Concomitant trastuzumab and immunecheckpoint inhibitors may enhance ADCC and, therefore, improve outcome.

# Objective

- To assess if the addition of different durations of avelumab to trastuzumab improves outcome in the adjuvant setting
- To explore the role of TILs and PD-L1 in predicting response to therapy

## Patient population

- HER2+/ER-
- Residual disease

## Study design

Neoadjuvant surgery RD R 1:1:1 treatment

Trastuzumab x 1 year N=50

Trastuzumab x 1 year + avelumab x 1 year N=50

Trastuzumab x 1 year + avelumab x 6 months N=50

## Endpoints

- Primary: DFS
- Secondary: OS, QoL, irAEs

 Strafication factors: TILs, PD-L1, previous chemo, ypN+

#### Traslational study

- TILs pre and post
- PD-L1 pre and post
- ctDNA

#### Thank you on behalf of the TRAVEL study steering committee

