The BACKGROUND of the study is that positive clinical investigations-1 demonstrated the mechanism of action of pelareorep and atezolizumab (2 to 5) will undergo close monitoring to evaluate safety of the combination. Once completed the treatment period of 3 patients, the recruitment will be stopped until evaluation by the Steering Committee.

The PRIMARY OBJECTIVE is to evaluate CellTIL score increase at 3 weeks of treatment of each cohort.

The KEY SECONDARY and EXPLORATORY OBJECTIVES include:
- To describe safety and tolerability of the different drug combinations.
- To evaluate biological changes to predict response to study drug(s), including breast cancer-related genes and a panel of 770 immune-related genes.
- To examine CD4 and CD8-T cell reactivity between baseline and treated samples.
- To evaluate whether pelareorep with different therapies induce different immune blood markers, such as changes in peripheral blood mononuclear cells.

The PATIENT STATUS is that up to date 6 patients have been included in the study. After the safety phase (3 subjects), recruitment re-started (Figure 4 and Table 3). There are currently 6 activated sites.

REFERENCES