**INTRODUCTION**

- **Combination treatment** with the cyclin-dependent kinase 4/6 (CDK4/6) inhibitor ribociclib (RIB) and endocrine therapy (ET) significantly improves efficacy outcomes compared with RIB + letrozole (LET) in patients with HR+, HER2- aBC.

**METHODS**

- **A high TKa value at baseline also correlated with worse PFS in patients in P3 (TKa high vs low: HR 0.9755; p=0.0012)**

**RESULTS**

- **Overall, 287 postmenopausal women were enrolled across 47 Italian centers (Table 1)**
- **Serum samples were collected at each time point (Figure 2)**
- **TKa levels at baseline and dynamic patterns**

**CONCLUSION**

**OBJECTIVE**

- **To assess serum TKa activity (TKa) as a prognostic and predictive biomarker of response to first-line treatment with RIB + letrozole (LET) in patients with HR+, HER2- aBC**

**METHODS**

- **BioItaLEE is a phase 3b, multicenter, single arm trial (NCT03439046) studying multiple potential biomarkers of response, their evolution during treatment, and their association with clinical outcomes in postmenopausal women with endocrine-sensitive HR+, HER2- aBC receiving RIB + LET as first-line therapy in Italy**

**METHODS (CONT...)**

- **The focus of this work is one of the secondary endpoints of the trial: the measurement of TKa levels and their association with clinical outcomes**
- **Serum samples were collected at baseline (DL), day 15 of cycle 1 (D15), day 1 of cycle 2 (C2D1), and at final imaging (FI, 12 weeks) (Figure 1)**

**CONCLUSION**

- **TKa appears to be a prognostic and predictive biomarker in patients with HR+, HER2- aBC treated with RIB + LET as first-line therapy**

**REFERENCES**


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