

Real-World Outcomes and Economic Impact of Ribociclib in HR+/HER2- Advanced Breast Cancer: Evidence from the Portuguese REASSURE Cohort

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KEY FINDINGS & CONCLUSIONS

- REASSURE was a European, non-interventional, retrospective cohort study involving patients with a/mBC treated with ribociclib. The Portuguese cohort included patients from *Instituto Português de Oncologia do Porto* who initiated ribociclib between January 2018 and September 2021.
- Ribociclib treatment demonstrated a median progression-free survival (PFS) of 31.2 months in Portuguese patients with a/mBC.
- The economic analysis highlights that outpatient care and all medication are the primary contributors to treatment costs.
- These findings provide valuable evidence for healthcare decision-makers regarding cost and resource implications of ribociclib in routine clinical practice.

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INTRODUCTION

- Breast Cancer (BC) is the most common cancer in women, with estimated 557,532 new cases in 2022 in Europe (24.3% of all new cancer cases)¹. Published data indicates that 5-10% of women diagnosed with BC have advanced disease with distant metastases²;
- For HR+/HER2- advanced/metastatic BC (ABC), CDK4/6 inhibitors have demonstrated efficacy in breast cancer and are currently used in different lines of treatment^{2,3};
- The REASSURE study aimed to evaluate real-world use of ribociclib, including its effectiveness, safety, and healthcare resource utilization (HCRU), in patients with HR+/HER2- advanced or metastatic breast cancer (a/mBC).

RESULTS

Patient characteristics

- A total of 81 patients with HR+/HER2- locally advanced/metastatic BC not amenable to curative surgery were included (median age: 59.0 years (51.0-68.0)) during the period 01-Jan-2018 to 30-Sep-2021. Most patients (n=68, 84%) were receiving ribociclib plus letrozole (Ribo+letrozole) (Figure 1).

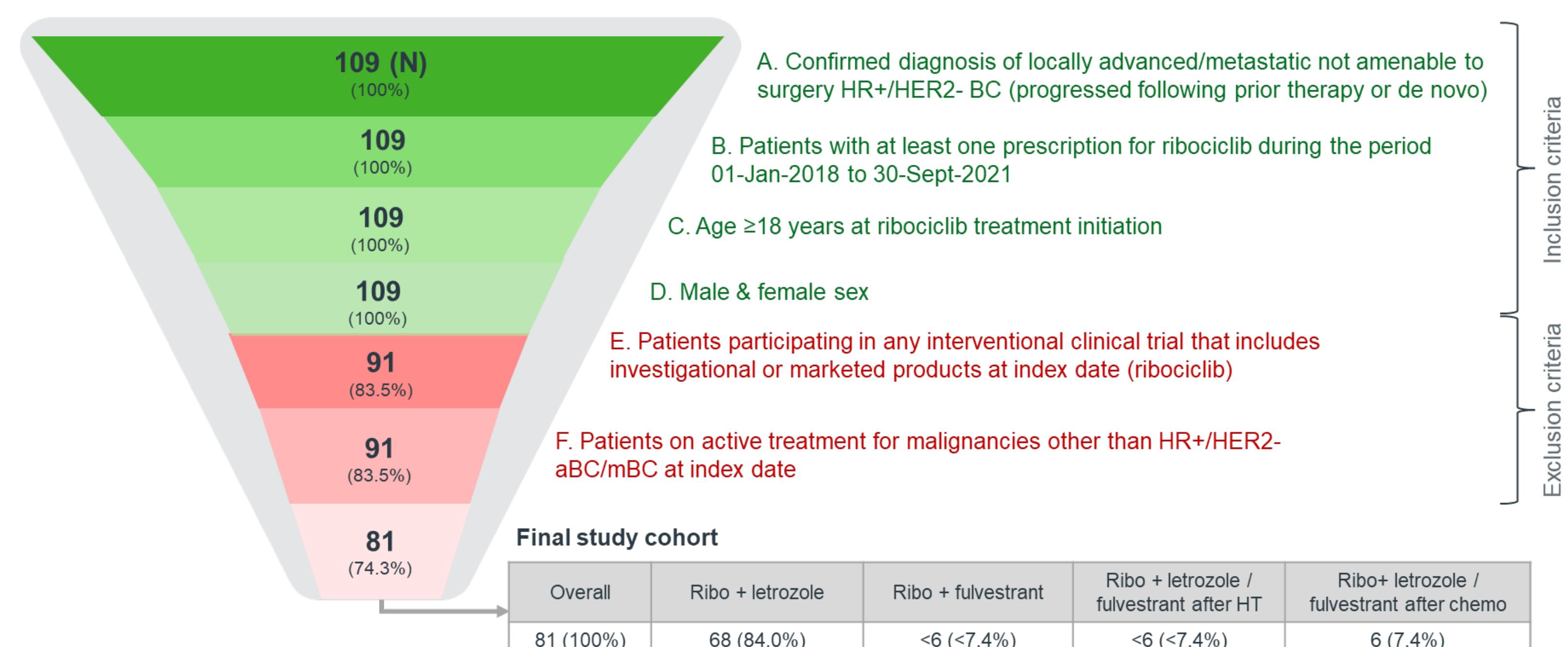


Figure 1 – Patient attrition

- Among the patients included, 75.3% were post-menopausal women and 64.2% were <65 years old.
- 38.3% had a single metastatic site. 58.0% of these patients presented a tumor grade 2 and 37.0% a tumor grade 3.
- 61.9% of these patients had asymptomatic mBC at index and 48.2% presented disease recurrence in ≤12 months.
- 85.2% (n=69) of ribo+letrozole group showed sensitivity to prior hormonal therapy (responded to prior endocrine therapy before progressing).

Clinical outcomes

- The median real-world progression-free survival (rwPFS) was 31.2 (18.6-NA) months from the date of ribociclib treatment initiation. Median overall survival (OS) was not reached (Figure 2).

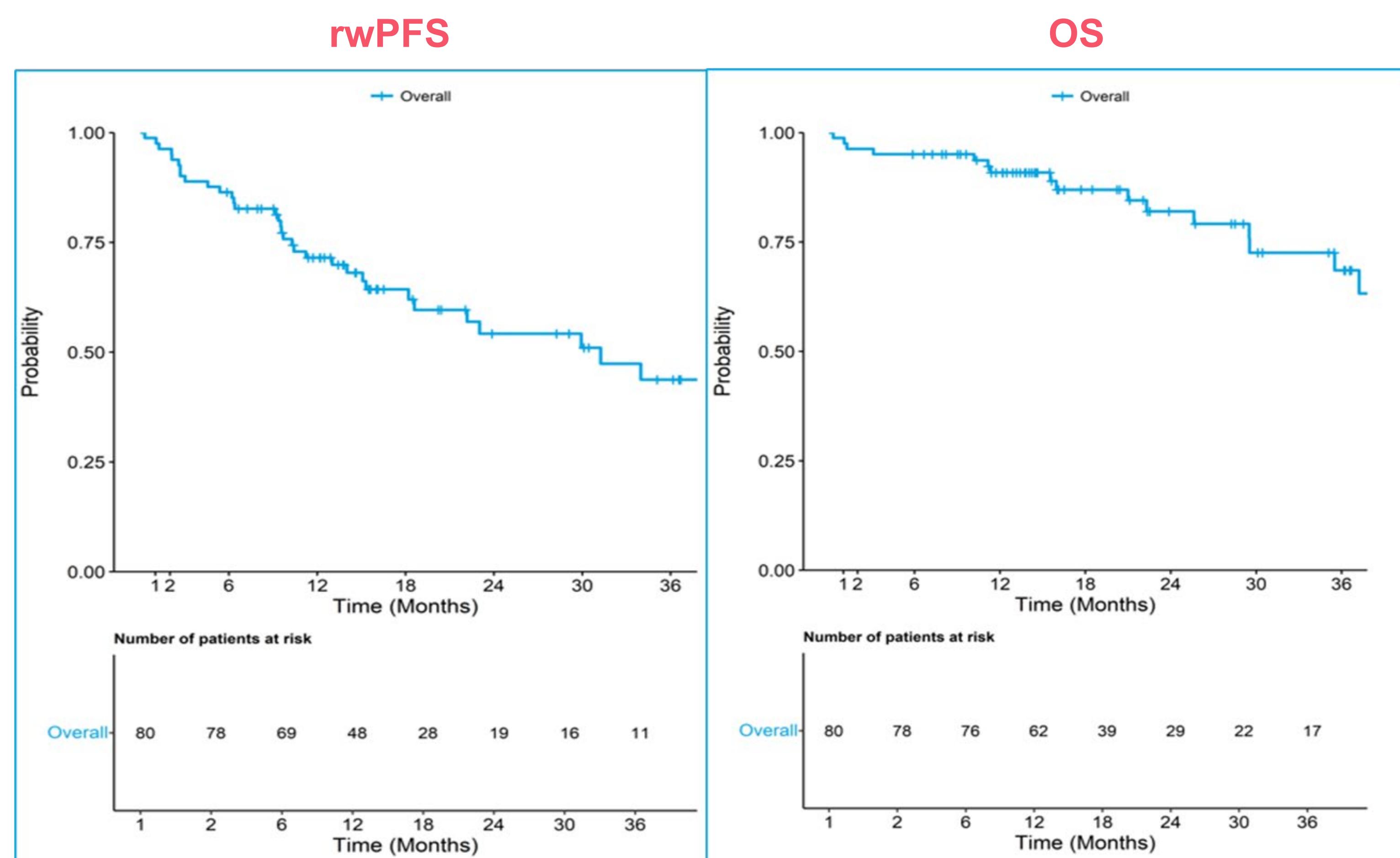


Figure 2 – rwPFS and OS for all included patients

METHODS

- REASSURE was a European, non-interventional, retrospective cohort study involving patients with a/mBC who were treated with ribociclib. Herein are highlighted the results from the Portuguese cohort.
- The Portuguese cohort included patients from *Instituto Português de Oncologia do Porto* who initiated ribociclib between January 2018 and September 2021. A 6-month lookback period (pre-index) and a minimum of 6 months follow-up, after the end of the index period was allowed. Data were extracted from electronic medical records and Cancer Registry.
- Kaplan-Meier methods were used for time-to-event outcomes. HCRU and direct medical costs were estimated from recorded procedures, hospitalizations, and outpatient care.

- The overall response rate (ORR) for the totality of included patients was 39.5% (n=32) with a median time-to-treatment failure (TTTF) of 22.1 (5.4-NA) months.
- The time to overall response was 3.7 (2.7-6.9) months.
- The duration of overall response (DoR) was 31.0 (13.2-NA) and the clinical benefit rate (CBR) was 69.1% (n=56).
- Treatment discontinuation occurred in 49.4% of patients, primarily due to progression or adverse events (18.5%). 54.3% of patients (n=44) did not require dose adjustments after ribociclib treatment initiation.

HCRU analysis

- Median emergency room stay min. was 161.0, and the median number of outpatient appointments was 51.0.
- Despite resource usage being higher for ER stay, costs were primarily driven by outpatient care and medication, with median values of €14,994.40 and €11,993.60, respectively, for the total included patients.

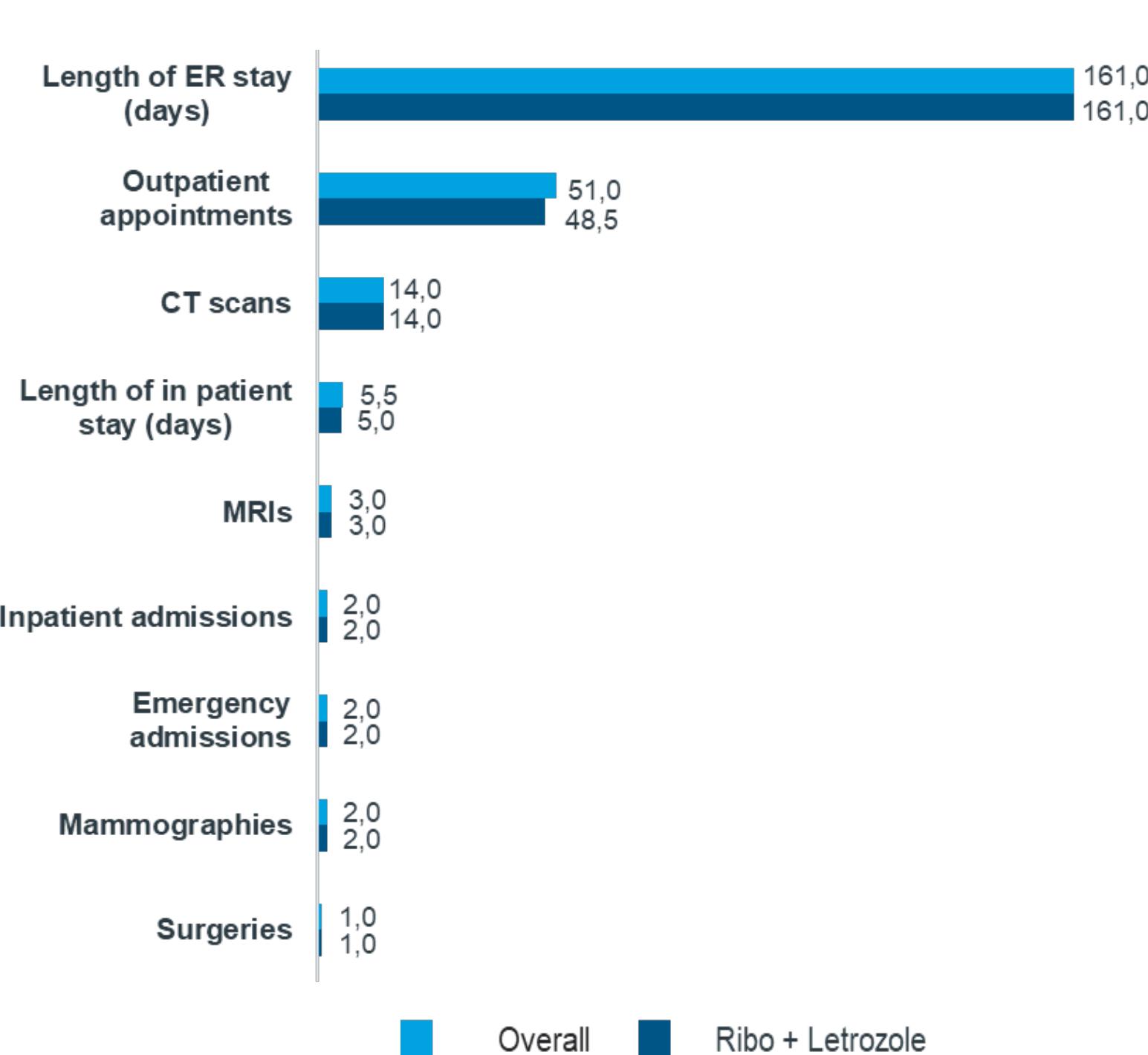


Figure 4 – Median number of admissions and procedures

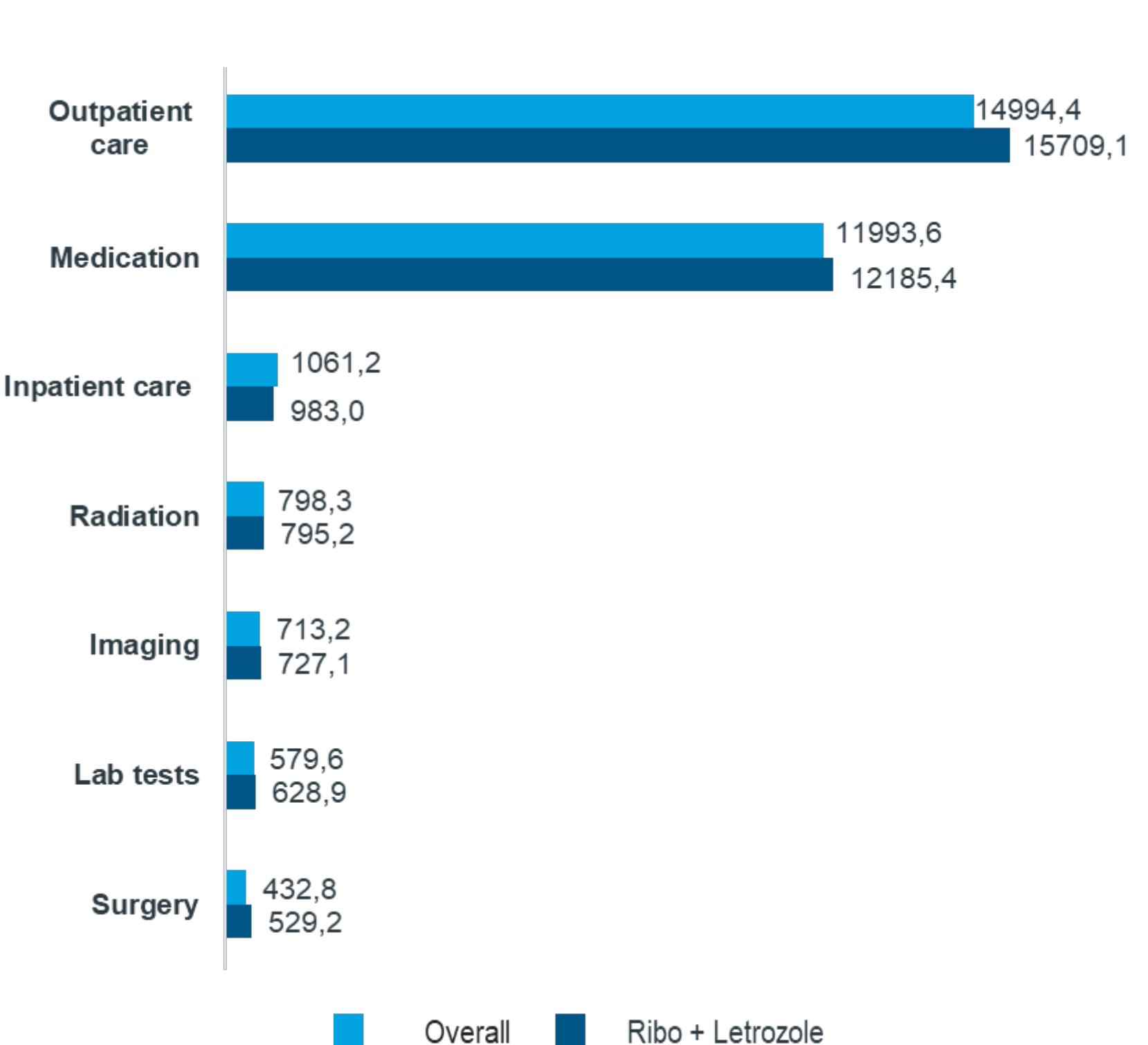


Figure 5 – Median annual treatment costs

References

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Disclosures

Marco Domingues is currently employee of Eli Lilly and Company.