Background and importance Palbociclib and ribociclib are novel oral agents in hormone receptor positive (HR+) and human epidermal growth factor 2 negative (HER2–) metastatic breast cancer (MBC). As these drugs have recently been released, it is necessary to provide insight into their real world use.

Aim and objectives The aim of this study was to provide data on effectiveness in patients treated with palbociclib and ribociclib in clinical practice.

Material and methods This observational retrospective study was performed in a tertiary hospital and included HR+/HER2– MBC patients who initiated treatment with palbociclib or ribociclib (March 2018 to March 2019). Patients were followed-up until March 2020. Patient demographics, clinical characteristics and treatment patterns were obtained from electronic medical records and the pharmacy database, Farmatools. The primary effectiveness variable was progression free survival (PFS). Overall survival (OS), and survival probabilities at 12 and 18 months were also estimated. OS was estimated with the Kaplan-Meier test and PFS with a competitive risk analysis, using the software R (V 2013).

Results 61 patients were enrolled: 33 treated with palbociclib and 28 with ribociclib. Median follow-up was 12.2 and 15.2 months in the palbociclib and ribociclib groups, respectively. Median age was 59 years (40–86). Eastern Cooperative Oncology Group Performance Status (ECOG PS) was 0–1 in most patients. Palbociclib was mainly used as second line (n=27; 81.8%) and ribociclib as first line (n=19; 67.9%) treatment. Treatment was discontinued in 24 patients (72.7%) receiving palbociclib and in 12 patients (42.9%) receiving ribociclib. Disease progression was the most common reason for discontinuation: 21 patients (63.6%) receiving palbociclib and 9 patients (32.1%) receiving ribociclib. In the palbociclib group, median PFS was 12.7 months (95% CI 34 to not estimable) and the 12 month and 18 month PFS rates were 51.5% (95% CI 34 to 69) and 37.7% (95% CI 20.1 to 55.4), respectively. Median duration of PFS was not reached in the ribociclib group; the 12 month and 18 month PFS rates were 87.1% (SE 7%) in the ribociclib group.

Conclusion and relevance Our findings in the real world setting confirmed the clinical benefit for women with HR+/HER2– MBC. Palbociclib and ribociclib outcomes were comparable with those reached in the phase III trials, PALOMA-3 and MONALEESA-2, due to the profile of the patients treated with both drugs. As palbociclib and ribociclib were used in different settings, outcomes cannot be compared.