

REAL-WORLD SAFETY AND TOLERABILITY OF THE RECENTLY COMMERCIALIZED PALBOCICLIB

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INDICATION: Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative **locally advanced or metastatic breast cancer** in combination with an aromatase inhibitor or fulvestrant (in women who have received prior endocrine therapy).

MOST COMMON ADVERSE EVENTS (AE): HEMATOLOGICAL

NO - HEMATOLOGICAL { INFECTIONS (54,7%)

NEUTROPENIA (80,6%) → MOST COMMON AE

LEUCOPENIA (45,2%)

ANEMIA (27,6%)

GRADE 3 → 55,3%

GRADE 4 → 10,1%

MEDIAN TIME FOR THE FIRST NEUTROPENIA EPISODE WAS 15 DAYS WITH A MEDIAN DURATION OF 7 DAYS.

PURPOSE:

TO EVALUATE THE **SAFETY OF PALBOCICLIB** IN REAL-WORLD CLINICAL PRACTICE AND COMPARE IT WITH THE RESULTS OF CT.

MATERIAL AND METHODS:

- PROSPECTIVE OBSERVATIONAL ANALYSIS (FEBRUARY-OCTOBER/2018) ON PATIENTS TREATED WITH PALBOCICLIB, IN A REGIONAL HOSPITAL.
- **PATIENTS' DEMOGRAPHICS** AND TREATMENT EVOLUTION RELATED TO TOXICITY WERE ANALYZED.
- TOXICITY GRADE WAS CLASSIFIED BY **CTCAE V5.0**.
- IN EACH VISIT, THE **PHARMACIST** REVISED PHYSICIAN'S PRESCRIPTION ACCORDING TO PATIENT'S ANALYSIS RESULTS AND MADE RECOMMENDATIONS.



RESULTS:

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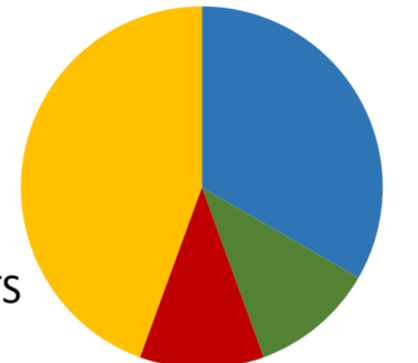


DIAGNOSTIC:

Metastatic breast cancer
HR-positive/HER2-negative

PREVIOUSLY TREATED WITH

- HORMONAL THERAPY
- CHEMOTHERAPY
- BOTH
- NO TREATMENTS



ACCORDING TO PRIOR TREATMENTS:

5 WOMEN RECEIVED PALBOCICLIB IN COMBINATION WITH AN AROMATASE INHIBITOR AND **4** WITH FULVESTRANT

- THE **MEDIAN NUMBER OF CYCLES** RECEIVED PER PATIENT WAS 4.5 (3-7).
- ALL PRESENTED **NEUTROPENIA** IN G3 (78%) OR G1-2 (22%), EXPERIENCED IT AFTER THE FIRST 15 DAYS OF TREATMENT AND ALTHOUGH RECOVERED, REAPPEARED IN ULTERIOR CYCLES, LEADING TO VARIOUS DISCONTINUATIONS IN 7 PATIENTS (DELAYS OR INTERRUPTIONS OF 7-14 DAYS).
- 66% NEEDED **DOSE REDUCTIONS** DOWN TO 100 OR 75 MG, BUT NO ONE HAD TO STOP TREATMENT.
- OTHER **AE** WITH AN INCIDENCE <24% WERE: RASH AND STOMATITIS G2, ASTHENIA, DIARRHEA, LEUCOPENIA AND ANEMIA G1.
- NO **INFECTIONS** WERE REPORTED.

CONCLUSION:

IN CLINICAL PRACTICE, THE PROPORTION OF PATIENTS AFFECTED BY **NEUTROPENIA WAS HIGHER** THAN IN CT WITH A 23% MORE INCIDENCE OF G3.

CLOSE MONITORING CONTRIBUTED TO MANAGING NEUTROPENIA AND PREVENTING ULTERIOR INFECTIONS.

IN THE FUTURE, IT WOULD BE INTERESTING TO EVALUATE IF DISCONTINUATIONS OR DOSE REDUCTIONS OF PALBOCICLIB **AFFECT ITS EFFICACY**.

