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RIBO-AGE: Age-stratified descriptive analysis of adverse events in patients with advanced breast cancer treated with Ribociclib plus nonsteroidal aromatase inhibitors: Preliminary Results

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KEY FINDINGS & CONCLUSIONS

- To our knowledge, this is one of the first safety-dedicated studies evaluating ribociclib + non-steroidal aromatase inhibitors in the Spanish healthcare setting.
- Preliminary data suggest that ribociclib in combination with NSAI is well tolerated in both younger and older patients with HR+/HER2− ABC.
- PFS preliminary outcomes appear consistent across age groups.
- Although the study is not powered for formal efficacy or safety comparisons between age cohorts, the final analysis of ≈500 patients will provide more defined insights into the real-world safety profile and treatment outcomes for this population.

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INTRODUCTION

- In Spain, 54% of women diagnosed with breast cancer are >65 years old.[1]
- Ribociclib, a CDK4/6 inhibitor, in combination with endocrine therapy (ET), has demonstrated significant improvements in progression-free survival (PFS) and overall survival in patients with hormone receptor-positive / human epidermal growth factor receptor 2-negative (HR+/HER2−) advanced breast cancer (ABC).[2-7]
- A pooled analysis demonstrated that ribociclib + ET is an effective and well-tolerated treatment for patients of all age groups with HR+ /HER2 − ABC, including older patients.[8]
- Despite these robust clinical trial outcomes, there is limited evidence on the use of ribociclib in older patients. Additionally, real-world data on the safety and tolerability of ribociclib + ET in Spain remain scarce.
- This study aims to provide new insights into the safety and tolerability profiles of ribociclib + non-steroidal aromatase inhibitors (NSAI) treatment in younger and older patients within the Spanish healthcare system.

OBJECTIVES

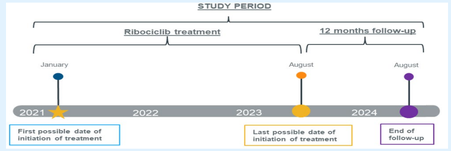
- The primary objective was to evaluate the age-specific safety and tolerability profile of ribociclib + NSAI as first-line therapy for HR+/HER2− ABC (metastatic/non-resectable) in routine clinical practice among Spanish adult patients.
- Secondary objectives analyzed in the preliminary analysis:
  - To assess the age-specific incidence of high-grade AEs during treatment with ribociclib + NSAI as first-line therapy for HR+/HER2− ABC (metastatic/non-resectable) among Spanish adult patients.
  - To determine and compare PFS in younger and older patients, with HR+/HER2− ABC (metastatic/non-resectable), who received at least one dose of ribociclib + NSAI as first line therapy.

METHODS

Study design and population

- This is a multicenter, non-interventional, retrospective, cohort study.
- Target population includes adult patients (≥18 years old) diagnosed with HR+/HER2− ABC and treated with ribociclib + NSAI in first line advanced/metastatic setting.
- All patients started treatment between January 2021 and August 2023, followed by a 12-month follow-up period to ensure adequate exposure to ribociclib to evaluate the occurrence of AEs (according to Common Terminology Criteria for AEs v5.0).
- Patients were grouped by age: <65 years, 65-75 years, and >75 years.
- Study sites reflect routine clinical management across various Spanish regions and data were collected exclusively from medical records.
- This preliminary analysis includes a subset of 147 patients from the overall study population. Data extraction is expected to conclude in November 2025, and the final analysis will include approximately 500 patients (**Figure 1**).

Figure 1. Study design



RESULTS

Sociodemographic and clinical characteristics

- A total of 147 patients were included (**Table 1**).

Table 1. Baseline sociodemographic and clinical characteristics

Variable		Total (n=147)	<65 years (n=108)	65-75 years (n=29)	>75 years (n=10)
Age, years	Mean (SD)	59.0 (11.6)	53.5 (7.5)	71.2 (3.1)	82.5 (5.8)
Sex, n (%)	Female	146 (99.3%)	107 (99.1%)	29 (100.0%)	10 (100.0%)
Menopausal status, n (%)	Valid n	136	98	28	10
	Premenopausal	28 (20.6%)	28 (28.6%)	0 (0.0%)	0 (0.0%)
	Perimenopausal	10 (7.4%)	10 (10.2%)	0 (0.0%)	0 (0.0%)
	Postmenopausal	98 (72.1%)	60 (61.2%)	28 (100.0%)	10 (100.0%)
Comorbidities (≥5%), n (%)	Valid n	144	105	29	10
	Hypertension	27 (18.8%)	13 (12.4%)	9 (31.0%)	5 (50.0%)
	Diabetes	14 (9.7%)	6 (5.7%)	6 (20.7%)	2 (20.0%)
Number of metastatic sites, n (%)	Valid n	135	99	26	10
	1	64 (47.4%)	47 (47.5%)	14 (53.9%)	3 (30.0%)
	2	45 (33.3%)	32 (32.3%)	7 (26.9%)	6 (60.0%)
	3 and more	26 (19.3%)	20 (20.2%)	5 (19.2%)	1 (10.0%)

SD: standard deviation.

- 59.7% of the patients reported comorbidities at baseline (48.6% of the <65 years, 86.2% of the 65-75 years and 100.0% of the >75 years).

Table 2. Ribociclib: dose and discontinuation

Variable		Total (n=147)	<65 years (n=108)	65-75 years (n=29)	>75 years (n=10)
Ribociclib starting dose n (%)	400 mg	4 (2.7%)	1 (0.9%)	1 (3.5%)	2 (20.0%)
	600 mg	143 (97.3%)	107 (99.1%)	28 (96.6%)	8 (80.0%)
Ribociclib temporary interruption, n (%)	Yes	88 (59.9%)	68 (63.0%)	15 (51.7%)	5 (50.0%)
Dose at resuming after temporary interruption, n (%)	Valid n	87	67	15	5
	200	2 (2.3%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
	400	20 (23.0%)	15 (22.4%)	5 (33.3%)	0 (0.0%)
	600	65 (74.7%)	52 (77.6%)	10 (66.7%)	3 (60.0%)
Ribociclib discontinuation, n (%)*	Yes	72 (49.0%)	52 (48.2%)	15 (51.7%)	5 (50.0%)

*The details of the discontinuations are shown in Table 3.

Safety and tolerability profile

- The median follow-up was 23.8 months (range: 3.1 - 43.4), and the median time on treatment was 18.4 months (range: 0.5 - 43.4).
- Overall, the safety profile was consistent with previously reported data, with no new safety signals identified.
- Of the 147 patients of the analysis, 16 discontinued ribociclib due to AEs (10.9%) (**Table 3**).

Table 3. Reasons for discontinuation

Reason	Total (n=147)	<65 years (n=108)	65-75 years (n=29)	>75 years (n=10)
Adverse Event, n (%)	16 (10.9%)	10 (9.3%)	5 (17.2%)	1 (10.0%)
Disease progression, n (%)	45 (30.6%)	36 (33.3%)	7 (24.1%)	2 (20.0%)
Patient's decision, n (%)	2 (1.4%)	2 (1.9%)	0 (0.0%)	0 (0.0%)
Death, n (%)	3 (2.0%)	0 (0.0%)	1 (3.4%)	2 (20.0%)
Other, n (%)	5 (3.4%)	4 (3.7%)	1 (3.4%)	0 (0.0%)
Missing, n (%)	1 (0.7%)	-	1 (3.4%)	-

Table 4. Frequency of safety and tolerability AEs (≥10%)

Variable	Total (n=147)	<65 years (n=108)	65-75 years (n=29)	>75 years (n=10)
AE Global, n (%)*	141 (95.9%)	104 (96.3%)	28 (96.6%)	9 (90.0%)
AE Safety, n (%)**	129 (87.8%)	93 (86.1%)	27 (93.1%)	9 (90.0%)
Neutropenia	108 (73.5%)	81 (75.0%)	21 (72.4%)	6 (60.0%)
Liver toxicity¥	29 (19.7%)	18 (16.7%)	9 (31.0%)	2 (20.0%)
Anaemia	28 (19.0%)	20 (18.5%)	7 (24.1%)	1 (10.0%)
AE Tolerability, n (%)µ	103 (70.1%)	76 (70.4%)	22 (75.9%)	5 (50.0%)
Nausea	30 (20.4%)	23 (21.3%)	6 (20.7%)	1 (10.0%)
Fatigue	30 (20.4%)	19 (17.6%)	7 (24.1%)	4 (40.0%)
Rash	23 (15.6%)	17 (15.7%)	5 (17.2%)	1 (10.0%)
Pain	22 (15.0%)	19 (17.6%)	3 (10.3%)	0 (0.00%)
Arthralgia	20 (13.6%)	19 (17.6%)	1 (3.4%)	0 (0.00%)

AE: adverse event; ALP: alkaline phosphatase; ALT: alanine transaminase; AST: aspartate aminotransferase; GGT: gamma-glutamyl transferase; HCP: health care professional. *AE Global: AEs Safety + AEs Tolerability. **AE Safety: AEs objectively measured by a test and assessed by HCP. ¥Liver toxicity include levels of AST, ALT, ALP, GGT, and bilirubin. µAE Tolerability: AEs subjectively reported by patients and assessed by HCP.

Table 5. Frequency of Grade 3 or higher AEs (aligned with AEs in Table 4)

Variable	Total (n=147)	<65 years (n=108)	65-75 years (n=29)	>75 years (n=10)
AE Global ≥G3, n (%)*	89 (60.5%)	68 (63.0%)	16 (55.2%)	5 (50.0%)
AE Safety ≥G3, n (%)**	86 (58.5%)	65 (60.2%)	16 (55.2%)	5 (50.0%)
Neutropenia	81 (55.1%)	63 (58.3%)	14 (48.3%)	4 (40.0%)
Liver toxicity¥	7 (4.8%)	3 (2.8%)	3 (10.3%)	1 (10.0%)
Anaemia	3 (2.0%)	3 (2.8%)	0 (0.0%)	0 (0.0%)
AE Tolerability ≥G3, n (%)µ	6 (4.1%)	5 (4.6%)	1 (3.4%)	0 (0.0%)
Nausea	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fatigue	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rash	1 (0.7%)	1 (0.9%)	0 (0.0%)	0 (0.0%)
Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Arthralgia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

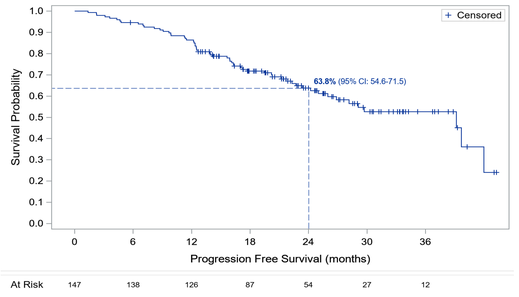
AE: adverse event; ALP: alkaline phosphatase; ALT: alanine transaminase; AST: aspartate aminotransferase; G3: Grade 3; GGT: gamma-glutamyl transferase; HCP: health care professional. *AE Global: AEs Safety + AEs Tolerability. **AE Safety: AEs objectively measured by a test and assessed by HCP. ¥Liver toxicity include levels of AST, ALT, ALP, GGT, and bilirubin. µAE Tolerability: AEs subjectively reported by patients and assessed by HCP.

PFS in younger and older patients

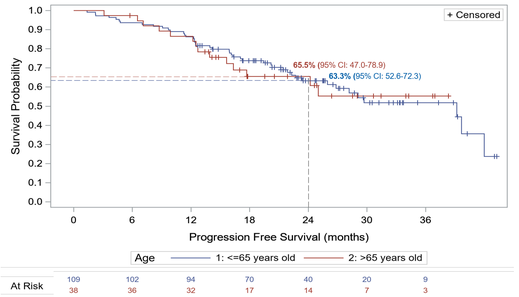
- In the total population (n=147), the median PFS was 39.2 months (95% CI: 26.9–42.0), while the PFS rate at 24 months was 63.8% (95% CI: 54.6–71.5), with similar rates among patients ≤65 years (63.3% [95% CI: 52.6–72.3]) and >65 years (65.5% [95% CI: 47.0–78.9]) (Figure 2).

Figure 2. Kaplan-Meier estimates of PFS

A. Total population



B. By age group (≤65 and >65 Years)



References

1. Torregrosa-Maicas MD, et al. Clin Transl Oncol. 2022;24:1033-46. **2.** Hortobagyi GN, et al. N Engl J Med. 2016;375:1738-48. **3.** Tripathy D, et al. Lancet Oncol. 2018;19: 904-15. **4.** Slamon D, et al. J Clin Oncol. 2018;36:2465-72. **5.** Hortobagyi GN, et al. N Engl J Med. 2022;386:942-50. **6.** Im SA, et al. *N Engl J Med*. 2019;381:307-16. **7.** Slamon DJ, et al. N Engl J Med. 2020;382:514-24. **8.** Hart LL, et al. Eur. J. Cancer. 2025;217:115225.

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