Addressing unmet clinical need in HR-positive/HER2–negative early breast cancer: baseline profile of Italian patients included in a compassionate use program with ribociclib plus NSAI

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Abstract

Ribociclib plus nonsteroidal aromatase inhibitor (NSAI) has been shown to significantly improve invasive disease-free survival (DFS) in patients with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative early breast cancer (EBC) at high risk of recurrence.

This retrospective analysis examined real-world data from Italian patients enrolled in a Managed Access Program (MAP), opened to allow access to ribociclib only to patients with HR-positive/HER2-negative EBC (stages II and III, based on NATALEE inclusion/exclusion criteria) with no other authorized treatment options available (no alternative CDK4/6 inhibitor indicated or accessible for their clinical profile).

From December 2024 to April 2025, 634 requests for ribociclib were approved. The average age of patients was 54.6 years, primarily consisting of female patients (99.2%). Most patients (95%) had stage II disease and had nodal involvement, mainly N1 (68.6%). Prior chemotherapy and adjuvant radiotherapy were administered to 46.7% and 49.2% of patients, respectively.

The findings highlight the pressing need for additional adjuvant treatment options for patients with HR-positive/HER2-negative EBC in Italy.

Introduction

Breast cancer is the most commonly diagnosed cancer worldwide, with HR-positive, HER2-negative breast cancer accounting for nearly three-quarters of all cases.[1]

The FDA and EMA recently approved ribociclib, in combination with an aromatase inhibitor, as an adjuvant therapy for HR-positive/HER2–negative EBC at high risk of recurrence, based on the phase 3 trial NATALEE findings, which showed improved invasive DFS for patients receiving ribociclib with NSAI.

To provide access to ribociclib, a MAP was established for eligible patients with **HR-positive/HER2-negative EBC (stages II and III)** according to the NATALEE criteria. This analysis assesses the baseline profiles of patients enrolled in the MAP for ribociclib in Italy.

Methods and Materials

This retrospective analysis utilized real-world data from Italian patients with HR-positive HER2-negative EBC stages II and III, who were approved for ribociclib treatment until the cut-off date April 2025.



The physicians submitted unsolicited requests, which were assessed against the eligibility criteria



The descriptive analysis reports patients:

- baseline profile-demographics
- clinical characteristics (tumor stage and biology)
- (neo-)adjuvant treatment patterns

Results

December 2024 — April 2025

Table 1. Baseline profile – Demographics

	Mean (SD)
Age[a] (years)	54.6 (10.9)
	n (%)
Male	5 (1)
Female	629 (99)
Menopausal status[b]	
Pre/Peri Menopausal	297 (47)
<40	45 (15)
≥40	252 (85)
Post Menopausal	332 (53)
<65	209 (63)
≥65	123 (37)
With at least one comorbidity	162 (26)
With concomitant medications	308 (49)

[a] Age at approval date
[b] Percentages were computed on female patients

Table 2. Disease characteristics – Nodal involvement[#]

Number of approved requests: 634						
N0 = 171 (27%)		N+ = 460 (73%)				
T2N0	T3-4N0	T0-1N1	T2N1	T3-4N1-2	AnyTN3	T0-3N2
145 (23)	26 (4)	221 (35)	211 (34)	5 (0.5)	12 (2)	11(1.5)

[#]Nodal status unknown: n =3

Figure 1. Nodal involvement and menopausal status

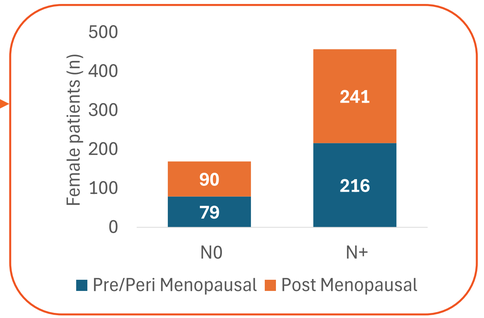


Table 3. Grading and Ki67 Expression Among Patients with T2N0

Grading T2N0	n (%)
Patient with T2N0 grade 2	53 (8)
Patient with T2N0 grade 3	91 (14)
Ki-67 T2N0 grade 2	**n (%)**
<20%	3 (6)
≥20%	29 (55)
Not Available	21 (40)

Table 4. Previous treatment patterns

Treatment	N0, n (%)	N+, n (%)	n
Chemotherapy	105 (35.5)	191 (64.5)	296
Adjuvant setting	80 (27.0)	147 (49.7)	227
Neoadjuvant setting	25 (8.5)	44 (14.9)	69
Adjuvant CDK4/6 inhibitor	15 (2.4)		
Proportion of overlap patient	4 (0.6)		
Reason for not being treated with abemaciclib			
Concomitant clinical conditions	2 (50)		
Outside treatment time window	2 (50)		

Discussion

These real-world data underscore the need for additional adjuvant treatment options in patients with HR-positive/HER2-negative EBC in Italy. Participants included a variety baseline characteristics, such as patients with stage II disease and those without nodal involvement, both with limited current treatment options. Importantly, all patients included in the MAP were not candidates for other CDK4/6 inhibitors in the adjuvant setting.

Conclusions

There is a need for more adjuvant treatments for HR-positive/HER2-negative EBC in Italy.

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References

1. Hortobagyi GN, et al. "A phase III trial of adjuvant ribociclib plus endocrine therapy versus endocrine therapy alone in patients with HR-positive/HER2-negative early breast cancer: final invasive disease-free survival results from the NATALEE trial". Ann Oncol. 2025 Feb;36(2):149-157. doi: 10.1016/j.annonc.2024.10.015.

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