Early breast cancer: Systemic treatments

# 230P - Health-related quality of life (HRQoL) in patients (pts) with HR+/HER2− early breast cancer (EBC) receiving adjuvant ribociclib (RIB) plus a nonsteroidal aromatase inhibitor (NSAI) vs NSAI alone: NATALEE 5-y outcomes

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Speakers Peter A. Fasching (Erlangen, Germany)
Presentation Topic Early breast cancer: Systemic treatments
Time 13:15 - 14:15

Abstract

## Background

In the phase 3 NATALEE trial, adjuvant RIB + NSAI showed statistically significant invasive disease–free survival benefit vs NSAI alone in pts with stage II/III HR+/HER2− EBC. The primary 3-y HRQoL analysis showed that adding adjuvant RIB to NSAI did not negatively impact HRQoL. Here, we present an updated 5-y analysis of HRQoL in NATALEE (data cutoff: May 28, 2025).

## Methods

NATALEE randomized pts with stage II/III HR+/HER2− EBC (with additional high-risk criteria for stage IIA N0 G2) to treatment (tx) with RIB (3 y) + NSAI (≥5 y) or NSAI (≥5 y) alone. EORTC QLQ-C30 and QLQ-BR23 functional scales (global health status [GHS], physical functioning [PF]) and symptom scales (upset by hair loss [HL], constipation [CO], diarrhea [DI], nausea and vomiting [NV], fatigue [FA]) were assessed. A mixed model for repeated measures (MMRM) determined mean change from baseline (BL) over time (scores higher than BL = improvement for functional scales; scores lower than BL = improvement for symptom scales). Time to first deterioration (TTFD [≥10%]) determined risk of worsening from BL.

## Results

Compliance with completing patient-reported outcome questionnaires was high in both arms (≈93%-100%). For all scales, MMRM analysis showed no minimally important difference (MID) from BL in either arm or between arms (Table). TTFD did not differ between RIB and NSAI arms, apart from slight trends favoring NSAI alone for CO, NV, and FA. However, throughout the 3-y RIB tx period, most pts were not bothered by or did not experience symptoms of HL, CO, DI, NV, or FA (>70% “not at all” or “a little”). At 5 y, these symptoms scores were similar or lower with RIB + NSAI vs NSAI. **Table: 230P**

| | Mean Δ BL[a,b] | | | TTFDHR (95% CI) |
|---|---|---|---|---|
| | RIB + NSAI | | NSAI | |
| | ≈3 m | ≈1 y | ≈3 y | ≈5 y |
| GHS | −2.27 | −2.95 | −3.26 | −1.95 |
| PF | −1.57 | −1.53 | −1.76 | −2.05 |
| HL[c] | −0.36 | 5.99 | 2.55 | −0.43 |
| CO | 5.02 | 5.55 | 5.26 | 2.38 |
| DI | 0.90 | 1.37 | 1.73 | 2.67 |
| NV | 2.00 | 2.11 | 2.61 | 0.87 |
| FA | 2.99 | 3.30 | 4.11 | 2.40 |

| | ≈3 m | ≈1 y | ≈3 y | ≈5 y | TTFDHR (95% CI) |
|---|---|---|---|---|---|
| GHS | −1.74 | −2.09 | −1.85 | −1.80 | 1.06 (0.99-1.14) |
| PF | −1.82 | −1.90 | −1.45 | −1.55 | 1.01 (0.94-1.10) |
| HL[c] | −8.21 | −2.74 | 0.72 | 4.21 | 1.27 (0.99-1.63) |
| CO | 1.00 | 1.92 | 2.23 | 2.63 | 1.31 (1.21-1.42) |
| DI | 0.53 | 1.11 | 2.46 | 3.22 | 1.08 (0.99-1.18) |
| NV | 0.14 | 1.21 | 1.33 | 1.44 | 1.33 (1.23-1.44) |
| FA | 1.94 | 1.89 | 2.10 | 2.05 | 1.12 (1.04-1.19) |

[a] MID from BL: GHS, −5 /+5; PF, −5/+2; CO, 5 /−4; DI, 5/−3; NV, 5/−3; FA, 5/−4 (Cocks 2012). [b] MID between arms: GHS, −4/+4; PF, −5/+5; CO, 5/−5; DI, 3/−3; NV, 3/−3; FA, 5/−5 (Cocks 2011). [c] MID from BL: 25.64 (SD, 0.5).

## Conclusions

Consistent with prior analyses, this updated 5-y analysis, with all pts off RIB for a median of 2 y, shows that HRQoL was maintained with adjuvant RIB + NSAI vs NSAI alone in pts with HR+/HER2− EBC.

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## Legal entity responsible for the study

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## Disclosure

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