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Pooled analysis of patient (pt)-reported outcomes (PROs) in the MONALEESA (ML)-2, -3, and -7 trials: additional results and key subgroup findings

Background: The Phase III ML-2, -3, and -7 trials assessed ribociclib (RIB) with different endocrine therapy (ET) partners in pts with hormone receptor–positive, HER2-negative (HR+/HER2−) advanced breast cancer (ABC). Quality-of-life (QOL) results were previously reported for each ML trial and as a pooled analysis. Here, we report on individual dimensions of the EORTC QLQ-C30 PROs, including relevant pt subgroup data from a pooled analysis of the ML trials.

Methods: PROs were collected with EORTC QLQ-C30 questionnaires. QOL was assessed for all pts in ML-2, pts without prior ET for ABC in ML-3, and pts receiving RIB or placebo (PBO) + a nonsteroidal aromatase inhibitor in ML-7. A linear effects model was used to calculate the least-squares mean changes from baseline in global health status (GHS), nausea and vomiting, diarrhea, and anxiety/depression, and these were interpreted using minimally important differences. GHS was also assessed for pt subgroups including age, race, and molecular subtype by PAM50.

Results: A total of 1528 pts were included. Time to definitive deterioration (TDD) for diarrhea and anxiety/depression was prolonged for RIB vs PBO (Table). Diarrhea, anxiety/depression, and GHS across subgroups were improved or maintained from cycle 3 to end of treatment. Median TDD of GHS was longer for RIB vs PBO in pts regardless of age. Median TDD of GHS for RIB vs PBO was longer for White pts, similar for Asian pts, and shorter for pts of other races, although the n in the latter group was small. Median TDD of GHS for RIB vs PBO was longer in pts with luminal subtypes and was more than doubled for the HER2-enriched (HER2E; 30.4 vs 14.8 mo) subtype.

Conclusions: In this pooled analysis of the ML trials, RIB + ET showed delayed deterioration in QOL scores. TDD for GHS favored RIB vs PBO across most subgroups. These results support prior QOL analyses showing the value of RIB + ET in maintaining QOL for pts with HR+/HER2− ABC.

TDD, median mo	RIB + ET (n=819)	PBO + ET (n=709)	HR (95% CI)
All pts			
Nausea/vomiting ≥12 points	57.9	NE	1.04 (0.82-1.31)
Diarrhea ≥10 points	NE	55.2	0.76 (0.59-1.00)
Anxiety/depression ≥30%	52.0	49.7	0.78 (0.63-0.96)
Age (n)[a]			
<40 y (171)	35.9	23.0	0.78 (0.46-1.30)
40 - <55 y (531)	34.2	27.7	0.75 (0.57-0.99)
≥55 y (826)	42.6	35.9	0.82 (0.65-1.05)
Race (n)[a]			
Asian (254)	35.9	35.8	0.94 (0.60-1.46)
White (1131)	41.5	32.2	0.73 (0.59-0.89)
Other (143)	33.2	46.9	1.11 (0.61-2.00)
Molecular subtype (n)[a]			
Luminal A + B (628)	41.7	35.9	0.86 (0.65-1.14)
HER2E (105)	30.4	14.8	0.59 (0.29-1.20)
Basal-like (49)	16.5	22.4	0.84 (0.34-2.06)
Normal-like (152)	47.2	50.6	0.74 (0.41-1.32)

[a]GHS by ≥10%

NE, not estimable.