



**Consistently LONGEST OS Benefit**  
in 1L post-menopausal HR+/HER2-ABC  
regardless of endocrine partner<sup>2-9</sup>


**M2**  
1L POST-MENOPAUSAL  
KISQALI + AI  
24% RISK  
REDUCTION  
IN DEATH<sup>2</sup>



**M3**  
1L POST-MENOPAUSAL  
KISQALI + FUL  
33% RISK  
REDUCTION  
IN DEATH<sup>1</sup>



**M7**  
1L PRE-MENOPAUSAL  
KISQALI + AI + GOSERELIN  
20% RISK  
REDUCTION  
IN DEATH<sup>5</sup>



**M2 RIB+LET mOS 63.9mo**  
VS  
**PBO+LET mOS 51.4mo**  
(HR, 0.76; 95% CI, 0.63-0.93)<sup>2</sup>

**M3 1L RIB+FUL mOS 67.6mo**  
VS  
**PBO+FUL mOS 51.8mo**  
(HR, 0.67; 95% CI, 0.50-0.90)<sup>1</sup>

**M7 RIB+ET mOS 58.7mo**  
VS  
**PBO+ET mOS 47.7mo**  
(HR, 0.798; 95% CI, 0.615-1.035)<sup>5</sup>

MONALEESA-2: Phase 3, 1:1 randomized, double-blind, placebo-controlled trial in post-menopausal patients with HR+/HER2- ABC. As 1L in advanced disease, KISQALI 600 mg/day or PBO once daily (3 weeks on/1 week off) + letrozole 2.5 mg once daily continuously. N=668.<sup>10</sup> After median follow-up of 26.4 months, mPFS results: 25.3 months with KISQALI + letrozole vs 16.0 months in the PBO arm (HR=0.568; 95% CI: 0.457-0.704).<sup>11</sup>

MONALEESA-3: Phase 3, 2:1 randomized, double-blind, placebo-controlled trial in post-menopausal patients with HR+/HER2- ABC. As 1L or after 1L progression for advanced disease. KISQALI 600mg/day or PBO once daily (3 weeks on/1 week off) + FUL 500mg intramuscularly on day 1 of each 28-day cycle and day 15 of cycle 1. N=726.<sup>3</sup> After median follow-up of 39.4 months, 1L mPFS results: 33.6 months with KISQALI + FUL vs 19.2 months in the PBO arm (HR, 0.55; 95% CI, 0.42-0.72).<sup>3</sup> After median follow-up of 56.3 months, mOS results: 53.7 months with KISQALI + FUL vs 41.5 months in the PBO arm (HR, 0.726; 95% CI, 0.588-0.897).<sup>4</sup>

MONALEESA-7: Phase 3, 1:1 randomized, double-blind, placebo-controlled trial in pre- and perimenopausal patients with HR+/HER2- ABC. As 1L in advanced disease, KISQALI 600mg/day or PBO once daily (3 weeks on/1 week off) + NSAI (letrozole 2.5 mg or anastrozole 1 mg) or tamoxifen 20 mg orally once daily continuously + goserelin 3.6 mg subcutaneously on day 1 of each 28-day cycle. N=672. After median follow-up of 19.2 months, NSAI mPFS results: 27.5 months with KISQALI + NSAI + goserelin vs 13.8 months in the PBO arm (HR=0.57; 95% CI: 0.44-0.74).<sup>12</sup> After median follow-up of 53.5 months, NSAI mOS results: 58.7 months with KISQALI + NSAI + goserelin vs 47.7 months in the PBO arm (HR=0.80; 95% CI: 0.62-1.04); ITT mOS results: 58.7 months with KISQALI + ET + goserelin vs 48.0 months in the PBO arm (HR=0.76; 95% CI: 0.61-0.96).<sup>5</sup>

KISQALI is not indicated for concomitant use with tamoxifen.<sup>13</sup>

**Disclaimer:** None of the information is intended to promote or recommend any indication, dosage or other claim not covered in the licensed product information. Novartis does not support the promotion of its product in a manner inconsistent with its approved labelling. The MONALEESA-3 updated overall survival data was recently presented in the European Society for Medical Oncology (ESMO) Congress 2022 and is not yet approved in the Singapore PI. \*Neven P, Fasching PA, Chia S, et al. Updated overall survival results from the first-line population in the phase III MONALEESA-3 Trial of postmenopausal patients with HR+/HER2- advanced breast cancer treated with ribociclib + fulvestrant. Presented at: European Society of Medical Oncology; May 3-5, 2022.

1L, first-line; ABC, advanced breast cancer; CFS, chemotherapy-free survival; CI, confidence interval; FUL, fulvestrant; HER2-, human epidermal growth factor receptor 2- negative; HR, hazard ratio; HR+, hormone receptor-positive; M2, MONALEESA-2; M3, MONALEESA-3; M7, MONALEESA-7; mo, month; mOS, median overall survival; mPFS, median progression-free survival; PBO, placebo; PFS2, progression-free survival 2; OS, overall survival; y, year.

**References:** 1. Neven P, Fasching PA, Chia S, et al. Updated overall survival results from the first-line population in the phase III MONALEESA-3 Trial of postmenopausal patients with HR+/HER2- advanced breast cancer treated with ribociclib + fulvestrant. Presented at: European Society of Medical Oncology; May 3-5, 2022. 2. Hortobagyi GN, Stemmer SM, Burris HA, et al. Overall survival (OS) results from the phase III MONALEESA (ML)-2 trial of postmenopausal patients with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib (RIB). Presented at the European Society of Medical Oncology (ESMO) Congress, September 16-21, 2021, (Abstract #LBA17). 3. Slamon DJ, Neven P, Chia S, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. N Engl J Med. 2020;382(6):514-524. 4. Slamon DJ, Neven P, Chia S, et al. Ribociclib plus fulvestrant for postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer in the phase III randomized MONALEESA-3 trial: updated overall survival. Ann Oncol. 2021 May 15;S0923-7534(21)01553-2. 5. Tripathy D, Im S-A, Colleoni M, et al. Updated overall survival (OS) results from the phase III MONALEESA-7 trial of pre- or perimenopausal patients with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib. Presented at: San Antonio Breast Cancer Symposium; December 8-12, 2020; San Antonio, TX. Poster PD2-04. 6. Finn RS, Martin M, Rugo HS, et al. Palbociclib and letrozole in advanced breast cancer. N Engl J Med. 2016;375(20):1925-36. 7. Goetz MP, Toi M, Campone M, et al. MONARCH 3: abemaciclib as initial therapy for advanced breast cancer. Journal of Clinical Oncology. 2017;35(32):3638-46. 8. Turner NC, Slamon DJ, Ro J, et al. Overall survival with palbociclib and fulvestrant in advanced breast cancer. N Engl J Med. 2018;379(20):1926-36. 9. Sledge GW, Toi M, Neven P, et al. The effect of abemaciclib plus fulvestrant on overall survival in hormone receptor-positive, ERBB2-negative breast cancer that progressed on endocrine therapy—MONARCH 2: a randomized clinical trial. JAMA Oncology. 2020;6(1):116-24. 10. Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. N Engl J Med. 2016;375(18):1738-1748. 11. Hortobagyi GN, Stemmer SM, Burris HA, et al. Updated results from MONALEESA-2, a phase III trial of first-line ribociclib plus letrozole versus placebo plus letrozole in hormone receptor-positive, HER2-negative advanced breast cancer. 2018;29(7): 1541-1547. 12. Tripathy D, Im S-A, Colleoni M, et al. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor-positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial. Lancet Oncol. 2018; 19:904-15. 13. KISQALI Package Insert. Novartis Singapore; Jan 2022.SIN.



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