LATE BREAKING ABSTRACT: Ribociclib (RIB) plus tamoxifen (TAM) or a non-steroidal aromatase inhibitor (NSAI) in premenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (ABC): additional results from the MONALEESA-7 trial

Background: MONALEESA-7 (NCT02278120) is the first double-blind, randomized, Phase III trial evaluating the addition of RIB (cyclin-dependent kinase 4/6 inhibitor) to TAM or an NSAI vs placebo (PBO) + TAM/NSAI specifically in pre or perimenopausal patients (pts) with HR+, HER2– ABC. Here, we report additional data, including objective tumor response and health-related quality of life (HRQoL) outcomes in pts from MONALEESA-7.

Materials and methods: Pts who had received ≤1 line of prior chemotherapy and no prior endocrine therapy for ABC were randomized 1:1 to RIB (600 mg/day, 3-weeks-on/1-week-off) or PBO in combination with TAM (20 mg/day) or an NSAI (letrozole [2.5 mg/day] or anastrozole [1 mg/day]), and goserelin (3.6 mg every 28 days). Progression-free survival (PFS) was the primary endpoint; secondary endpoints included objective tumor response and duration of response (DoR).

Results: The study met its primary objective: PFS was significantly longer in the RIB + TAM/NSAI arm (n=335) vs the PBO + TAM/NSAI arm (n=337; hazard ratio: 0.553; 95% confidence interval [CI], 0.441–0.694; P=9.83×10⁻⁸); median PFS 23.8 months (95% CI, 19.2–not reached [NR]) vs 13.0 months (95% CI, 11.0–16.4), respectively. Subgroup analyses demonstrated consistent PFS benefits for RIB vs PBO, including in pts treated in Europe (n=255; hazard ratio: 0.648; 95% CI, 0.443–0.946). Among pts with measurable disease at baseline, 137/269 (51%; 95% CI, 45.0–56.9) and 100/275 (36%; 95% CI, 30.7–42.0) pts had a complete or partial response in the RIB + TAM/NSAI and PBO + TAM/NSAI arms, respectively (95% CI, 6.3–22.8; P=3.17×10⁻⁴). The probability of a response by 6 months was 35% (95% CI, 30.1–40.6) in the RIB + TAM/NSAI arm vs 25% (95% CI, 20.2–29.6) in the PBO + TAM/NSAI arm. A decrease in best percentage change from baseline in any tumor size was reported for 83% of pts in the RIB + TAM/NSAI arm and 71% of pts in the PBO + TAM/NSAI arm. The median DoR was 21.3 months (95% CI, 18.3–NR) for the RIB + TAM/NSAI arm and 17.5 months (95% CI, 12.0–NR) for the PBO + TAM/NSAI arm. At the first tumor evaluation (Week 8), a decrease in any tumor size was observed in 58% (193/335) of pts in the RIB + TAM/NSAI arm and 48% (163/337) of pts in the PBO + TAM/NSAI arm. The mean pain reduction from baseline was 20% in the RIB + TAM/NSAI arm and 14% in the PBO + TAM/NSAI arm at Week 8; pts receiving RIB + TAM/NSAI and PBO + TAM/NSAI had a median percentage change from baseline in EORTC QLQ-C30 pain symptom score of −33% and −17%, respectively.

Conclusions: In pre or perimenopausal women with HR+, HER2– ABC, RIB + TAM/NSAI and goserelin significantly prolonged PFS and was associated with a higher objective tumor response rate vs PBO + TAM/NSAI and goserelin. An early and durable tumor response, and a reduction in pain at Week 8 were also observed in the RIB + TAM/NSAI and goserelin arm.