

Supplemental Table 1. Ongoing clinical trials evaluating ribociclib[#] in patients with breast cancer

Register number (target accrual, N) Design, arms and regimen	Setting Study population	Primary outcome; Status
Antiestrogen		
NCT 01958021 (MONALEESA-2, N = 667) Phase 3, randomized, double-blinded, placebo-controlled. Letrozole ± Ribociclib.	Postmenopausal women with HR+/HER2-negative ABC (first line HT)	PFS; Accrual is complete.
NCT 02422615 (MONALEESA-3, N = 660) Phase 3, randomized, double-blinded, placebo-controlled. Fulvestrant ± Ribociclib.	Postmenopausal women with HR+/HER2-negative ABC, chemotherapy-naïve in the metastatic setting (first or second line HT)	PFS; Enrolling patients.
NCT 02278120 (MONALEESA-7, N = 660) Phase 3, randomized, double-blinded, placebo-controlled. Goserelin + NSAI (or Tamoxifen) ± Ribociclib .	Premenopausal women with HR+/HER2-negative ABC (first line HT)	PFS; Enrolling patients.
NCT 02333370 (N = 112) Phase 1b/2, open label, single arm. Letrozole ± Ribociclib.	Postmenopausal Asian women with HR+/HER2-negative ABC (first line HT)	PFS*; Enrolling patients.
NCT 02712723 (N = 120) Phase 2, randomized, double-blinded, placebo-controlled. Arm A: Letrozole + placebo, Arm B: Letrozole plus Ribociclib, Arm C: Letrozole plus Ribociclib (in this arm Ribociclib will be given at dose 400mg PO daily, continuously).	Postmenopausal women with HR+/HER2-negative ABC in which neoadjuvant endocrine therapy is suitable.	Rate of PEPI score 0; Enrolling patients.
NCT 02586675 (N = 40) Phase 1, open label. Ribociclib with goserelin with tamoxifen.	Women with HR+/HER2-negative ABC, no more than two prior lines of chemotherapy.	RP2D; Enrolling patients.
Triplet therapy		
NCT 01872260 (N = 200) Phase 1b/2, open label. Arm A: Ribociclib + Alpliseb + Letrozole; arm B: Letrozole + Alpliseb; Arm C: Letrozole plus Ribociclib.	Posmenopausal women with HR+/HER2-negative ABC (first line HT*)	Safety; Enrolling patients.
NCT 02088684 (N = 200) Phase 1b/2, open label. Arm A: Ribociclib + alpliseb plus fulvestrant; Arm B: Ribociclib plus BKM120 + fulvestrant; Arm C: Ribociclib + fulvestrant.	Posmenopausal women with HR+/HER2-negative ABC (first line HT*)	PFS*; Enrolling patients.
NCT 01857193 (N = 142) Phase 1b/2 open label. Arm A: Ribociclib + Everolimus + Exemestane Arm B: Ribociclib + Exemestane	Posmenopausal women with HR+/HER2-negative ABC, prior treatment with a NSAI for ABC is required, no more than one line of chemotherapy in the advanced setting.	Safety; Enrolling patients.
Anti-HER2 therapy		
NCT 02657343 (N = 86) Phase 1b, open label Arm A: Ribociclib plus trastuzumab; Arm B: Ribociclib plus T-DM1	Postmenopausal women with HR+/HER2-positive ABC, Cohort A: prior treatment with trastuzumab and taxane, no prior treatment with T-DM1, no more than four prior lines of therapy in the advanced setting Cohort B: must have prior treatment with trastuzumab, pertuzumab and in any disease setting, no limit on prior lines of therapies.	RP2D; Enrolling patients.

ABC: advanced breast cancer; DLTs: dose limiting toxicities; HR+: hormone receptor positive; HT: hormone therapy; NSAI: non-steroidal aromatase inhibitor (anastrozole or letrozole); ORR: objective response rate; PEPI: Pre-operative Endocrine Prognostic Index; RP2D: recommended phase 2 dose; T-DM1: trastuzumab-emtansine; TNBC: triple-negative breast cancer; [#]Ribociclib is given orally 600mg once daily, 3 weeks on and 1 week off ; *related to phase 2; ± with or without.

Supplemental Table 2. Ongoing clinical trials evaluating abemaciclib in monotherapy or in combination with other agents in patients with breast cancer

Register number (name of the study, target accrual) Design Arms and regimen	Patient population	Primary outcome; Status
Monotherapy		
NCT 02308020 (JPBO, N = 247) Phase 2, open label, single arm. Abemaciclib 200mg given PO twice daily.	Patients with brain metastasis secondary to HR-positive BC, NSCLC or melanoma.	OIRR; Enrolling patients.
In combination		
NCT 02107703 (MONARCH 2, N = 630) Phase 3, randomized, double-blinded, placebo-controlled Fulvestrant ± Abemaciclib 150mg given PO twice daily q28.	Postmenopausal women with HR+/HER2-negative ABC, chemotherapy-naive in the metastatic setting (first or second line of HT)	PFS; Accrual complete.
NCT 02246621 (MONARCH 3, N = 450) Phase 3, randomized, double-blinded, placebo-controlled NSAI (anastrozole or letrozole) ± Abemaciclib 150mg given PO twice daily q28.	Postmenopausal women with HR+/HER2-negative ABC, no previous systemic therapy in the metastatic setting (first line of HT)	PFS; Accrual complete.
NCT 02057133 (JPBH, N = 102) Phase 1b, open label, single arm. Abemaciclib in combination with: anastrozole (Part A), letrozole (Part B), tamoxifen (Part C), exemestane (Part D), exemestane + everolimus (Part E), or trastuzumab (Part F).	Patients enrolled in Parts A to E presents with HR+/HER2-negative ABC. Patient in Part F presents with HR+/HER2-positive ABC. Parts A and B (first line HT) Part C (prior treatment with HT is required) Parts D and E (prior treatment with a NSAI for ABC is required) Part F (prior treatment with at least 1 CT regimen for ABC).	Number of patients with one or more drug-related adverse events; Accrual complete.
NCT 02675231 (MonarcHER, N = 225) Phase 2, open label, randomized Arm A: Abemaciclib + trastuzumab plus fulvestrant, Arm B: Abemaciclib + trastuzumab, Arm C: Trastuzumab + CT.	Postmenopausal women with HR+/HER2-positive ABC, treated in third line or more (participant must have received T-DM1 and a taxane in any disease setting).	PFS; Enrolling patients.
NCT 02441946 (neoMONARCH, N = 220) Phase 2, open label, randomized Arm A: Abemaciclib + anastrozole, arm B: Anastrozole, Arm C: Abemaciclib. After 2 wks, participants will receive abemaciclib + loperamide PO every 12 hours plus anastrozole orally once daily for 14 wks.	Postmenopausal women with HR+/HER2-negative ABC in which neoadjuvant endocrine therapy is suitable.	Change from baseline to 2 wks in Ki67 expression; Enrolling patients.

ABC: advanced breast cancer; CT: chemotherapy; HR+: hormone receptor positive; HT: hormone therapy; OIRR: objective intracranial response rate; PFS: progression-free survival; PO: per os; NSAI: non-steroidal aromatase inhibitor; NSCLC: non-small cell lung cancer; wks: weeks; ±: with or without.