**abstracts**

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**ComplEEMent-1: Phase 3b study of ribociclib + letrozole for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2−) advanced breast cancer (ABC) in patients with no prior endocrine therapy (ET) for ABC**

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**Background:** CDK4/6 inhibitor ribociclib was recently approved in the United States in combination with letrozole for the treatment of HR+, HER2− ABC in postmenopausal women with no prior therapy for advanced disease, based on the significantly prolonged PFS versus placebo plus letrozole observed in the pivotal phase 3 MONALEESA-2 trial (Hortobagyi et al. NEJM 2016). The phase 3b ComplEEMent-1 study will further evaluate the safety and efficacy of ribociclib plus letrozole as first-line therapy in an expanded patient population.

**Trial design:** In this open-label study, men or women of any menopausal status with HR+, HER2− ABC will receive ribociclib (600 mg/day, 3 weeks on/1 week off) + letrozole (2.5 mg/day); men and premenopausal women will receive concomitant goserelin (3.6 mg subcutaneous implant every 28 days). Treatment will continue until disease progression or unacceptable toxicity. Patients are limited to ≤1 line of chemotherapy and no prior ET for advanced disease; patients receiving (neo)adjuvant ET with a non-steroidal aromatase inhibitor must have a disease-free interval of >12 months.

Exclusion criteria include Eastern Cooperative Oncology Group performance status >2, or prior CDK4/6 inhibitor treatment. Planned hematologic and chemistry laboratory assessments will be completed every 2 weeks for the first 2 months, then monthly to Cycle 6, and as clinically indicated to Cycle 36. Tumor assessments are recommended every 12 weeks or at intervals per local standard of care during the treatment phase. The primary outcome is safety and tolerability. Secondary outcomes include time to progression, clinical benefit rate, overall response rate, safety, and patient-reported outcomes (PROs). Adverse events and drug-drug interactions will be monitored using CT Scholar; PROs will be collected for female patients using the FACT-B questionnaire to better understand health-related quality of life and treatment side effects. Global recruitment of the planned ~1,000 patients is ongoing, with the majority occurring in Europe.

**Clinical trial identification:** NCT02941926

**Legal entity responsible for the study:** Novartis Pharmaceuticals

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