TPS617 **Poster Session**

Adjuvant WIDER: A phase 3b trial of ribociclib (RIB) + endocrine therapy (ET) as adjuvant treatment (tx) in a close-to-clinical-practice patient (pt) population with HR+/HER2− early breast cancer (EBC).

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Background: The phase 3 NATALEE trial met its primary endpoint with significant invasive disease–free survival benefit with RIB + ET vs ET alone in a broad pt population with stage II/III HR+/HER2− EBC, sustained with additional follow-up at 44.2 months (hazard ratio, 0.715). The Adjuvant WIDER trial will evaluate RIB + ET in an HR+/HER2− EBC pt population that reflects pts seen in clinical practice as it has wider eligibility criteria, including an additional focus on enrolling minority pts underrepresented in NATALEE. Given the unmet need in pts with Stage II/III EBC, the results of this trial will complement existing data on benefits of RIB + ET. **Methods:** This phase 3b, multicenter, open-label, single-arm trial will evaluate, with early involvement of key pt advocacy groups, the efficacy and safety of adjuvant RIB + ET in a close-to-clinical-practice pt population with HR+/HER2− EBC. Eligible women and men aged ≥18 years with an ECOG PS of 0 to 2 and anatomic stage II/III disease (AJCC 8th ed), with additional criteria for stage IIA disease (N1 or N0 with grade 3, or grade 2 with Ki-67 ≥20% or high genomic risk), will be included. Pts will receive RIB (400 mg/d; 3 wk on/1 wk off) + ET (letrozole 2.5 mg/d, anastrozole 1 mg/d, or exemestane 25 mg/d) for 36 months, followed by ET alone as SOC per investigator's clinical judgment. Pre/peri-menopausal women and men will receive goserelin 3.6 mg or leuprolide 3.75 mg/4 wk. Switching between ETs during study tx will be allowed in cases of unmanageable toxicity. Pts may have received (neo)adjuvant ET if initiated ≤36 months prior to enrollment. The number of pts with prior ET between 12 and 36 months will be capped at ≈30%; this cap will not be applicable to Black or African American pts. For pts with prior ET >12 months, restaging is recommended. Pts with prior CDK4/6i tx (except RIB) in the adjuvant setting for ≤6 months who discontinued due to toxicity can be included. Study tx may be held ≤28 days (or longer on agreement) to recover from RIB-related toxicity before restarting. If indicated, pts must have completed radiotherapy or chemotherapy before screening. Key exclusion criteria are distant metastases and/or recurrence and clinically significant, uncontrolled heart disease at screening. The primary endpoint is investigator-assessed invasive breast cancer–free survival rate at 3 years per STEEP v2.0 criteria. Secondary endpoints include invasive disease–free survival, distant disease–free survival, distant relapse–free survival, recurrence–free interval, overall survival, quality of life, and safety. Exploratory endpoints will assess subsequent antineoplastic tx, potential mechanisms of RIB benefit/resistance to RIB + ET, and RIB efficacy/safety in Black pts. Estimated enrollment is 1400 pts globally. Recruitment is ongoing. Clinical trial information: NCT05827081. Research Sponsor: Novartis Pharmaceuticals Corporation.