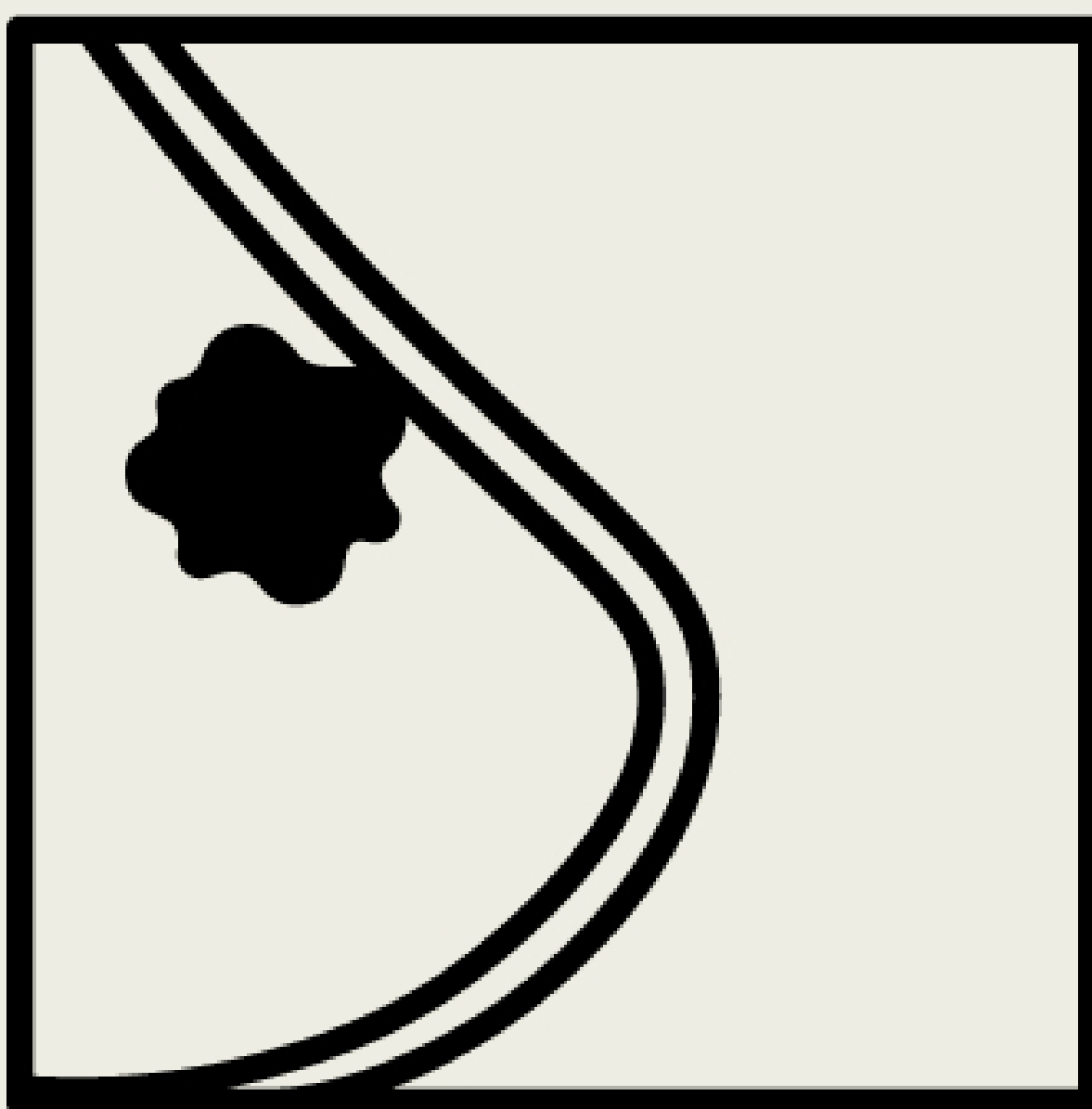


RCT: Ribociclib Plus Endocrine Therapy in Hormone Receptor-Positive/ERBB2-Negative Early Breast Cancer

POPULATION

20 Males, 5081 Females



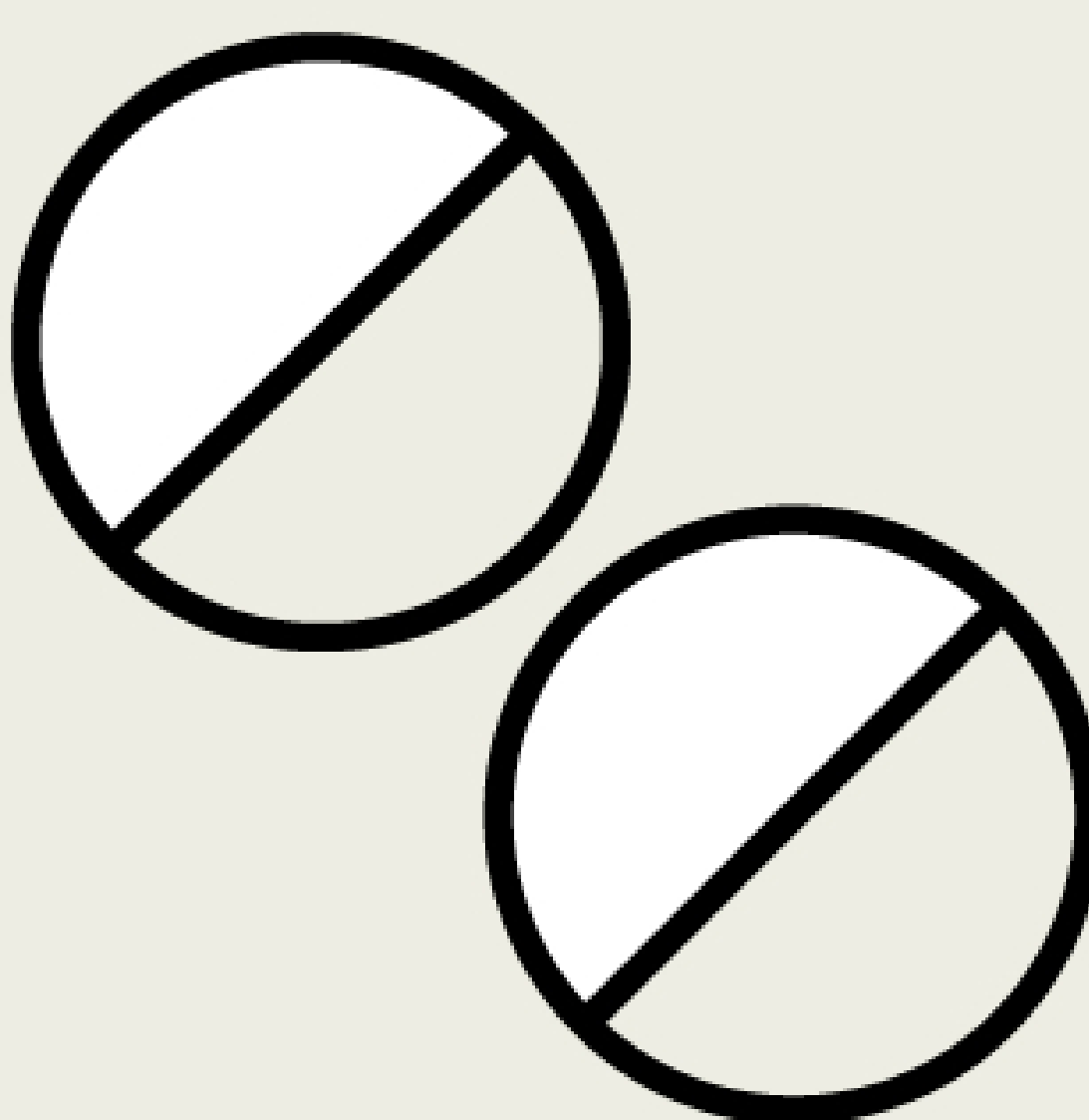
Adults with high-risk stage II or III hormone receptor-positive/ERBB2-negative early breast cancer
Median age: 52 (range, 24-90) y

SETTINGS / LOCATIONS

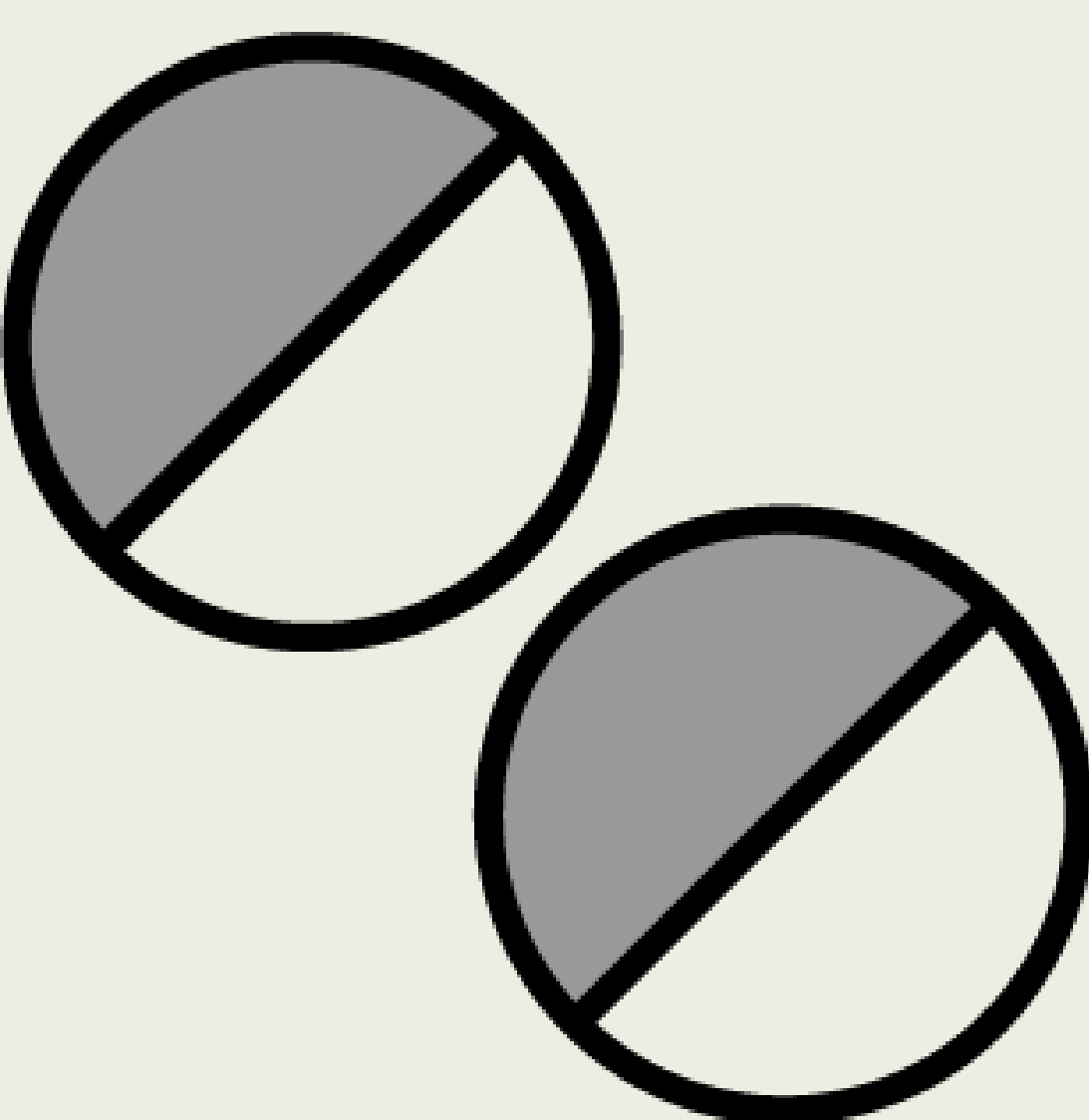
384 Sites in 20 countries

INTERVENTION

5101 Patients randomized



2549 Ribociclib plus nonsteroidal aromatase inhibitor (NSAI)
Experimental arm



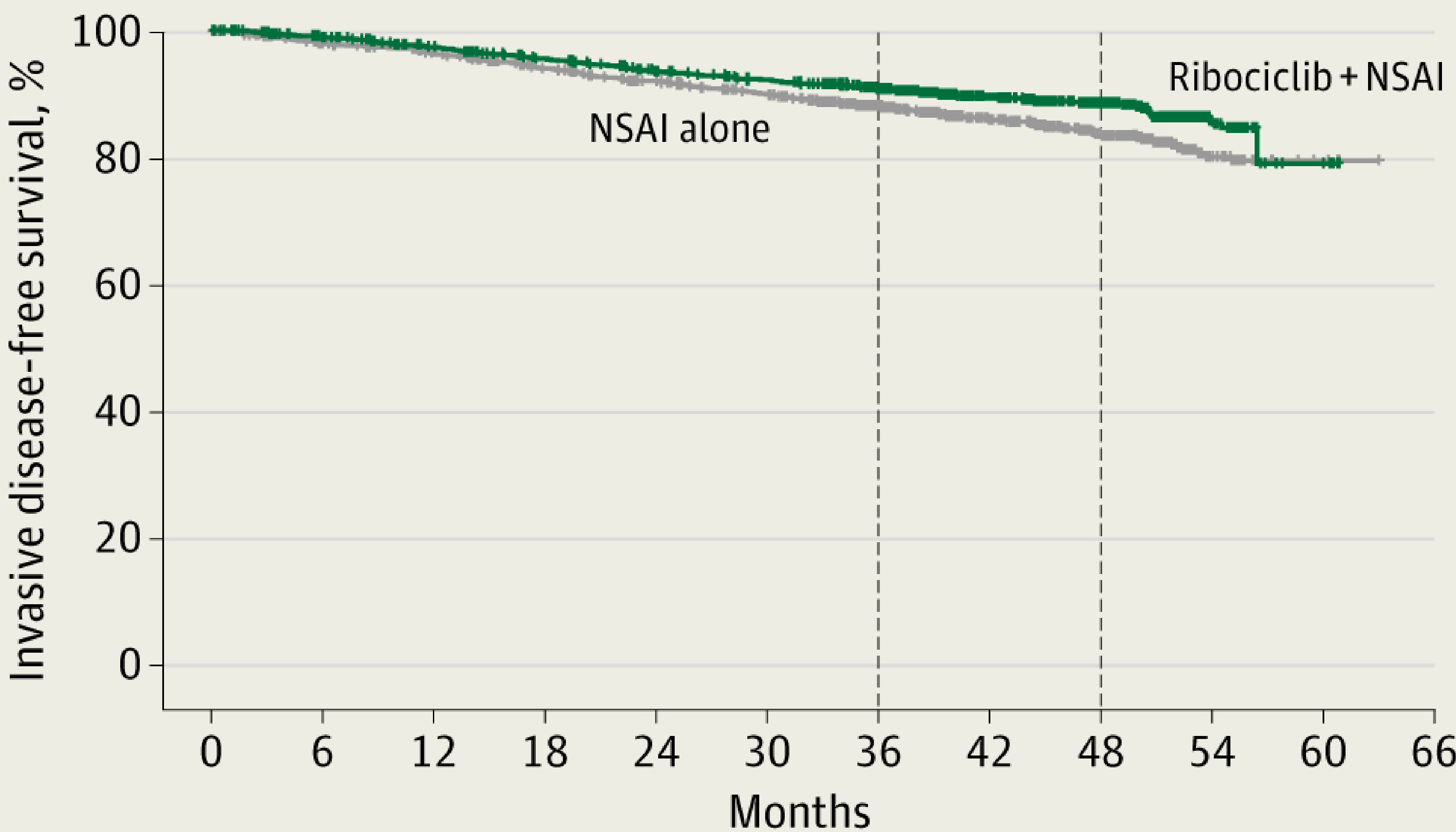
2552 NSAI alone
Control arm

PRIMARY OUTCOME

The primary end point was invasive disease-free survival (iDFS), which was defined according to Standardized Definitions for Efficacy Endpoints criteria, version 1.0, as assessed by the investigator

FINDINGS

With a median follow-up beyond the 3-y treatment duration and all patients completing or discontinuing ribociclib, there was consistent iDFS benefit with ribociclib plus NSAI vs NSAI alone



iDFS

Ribociclib + NSAI: 263 events (10.3%)
NSAI alone: 340 events (13.3%)
Hazard ratio: 0.72; 95% CI, 0.61-0.84