Adjuvant Abemaciclib Combined With Endocrine Therapy for High-Risk Early Breast Cancer: Updated Efficacy and Ki-67 Analysis From the monarchE Study

monarchE
EARLY BREAST CANCER

HR+, HER2-, node-positive, high-risk EBC

- ≥4 positive axillary lymph nodes (ALN)

OR

- 1-3 ALN and at least 1 of the below:
  - Tumor size ≥5 cm
  - Histologic grade 3
  - Centrally tested Ki-67 ≥20%

Randomized 1:1

Abemaciclib + Standard of Care Endocrine Therapy
(N=2808)

Standard of Care Endocrine Therapy
(N=2829)

- *Median duration of follow-up: 27 months*
- *Patients off study treatment period: 90%*

Intent to treat population
N=5637

Invasive disease-free survival (IDFS)
Primary objective

Abemaciclib + ET	ET alone

30% reduction in risk of developing an IDFS event
HR=0.70 (nominal p-value <0.0001)

2.7% absolute difference in **2-year IDFS rates**

92.7% — 90.0%

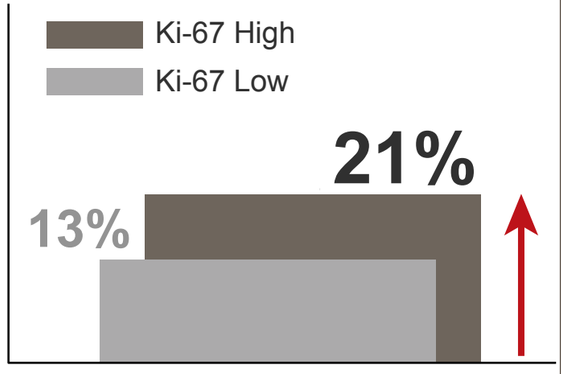
5.4% absolute difference in **3-year IDFS rates**

88.8% — 83.4%

Cohort 1
N=3917

Inclusion based on clinicopathological risk factors	**Ki-67 High** (≥20%) N=2003	**Ki-67 Low** (<20%) N=1914
Reduction in risk of developing an IDFS event	**37%** *HR=0.63 (p<0.001)*	**30%** *HR=0.70 Exploratory analysis*

Consistent treatment benefit in patients whose tumors had high clinicopathological risk factors, regardless of their Ki-67 index.



Risk of invasive disease at 3 years in control arm

Greater risk of recurrence in patients with high Ki-67 tumors, confirming the prognostic value of Ki-67.

- Abemaciclib + ET significantly reduced the risk of developing an IDFS event in patients with HR+, HER2-, node-positive, high risk EBC.
- The robust treatment benefit was confirmed and maintained beyond the 2-year treatment period with abemaciclib.