

Adjuvant abemaciclib combined with endocrine therapy for high-risk early breast cancer: updated efficacy and Ki-67 analysis from the monarchE study

Global, randomised, open-label, phase III trial of adjuvant ET for ≥ 5 years $\pm$ abemaciclib for 2 years (N = 5,637)

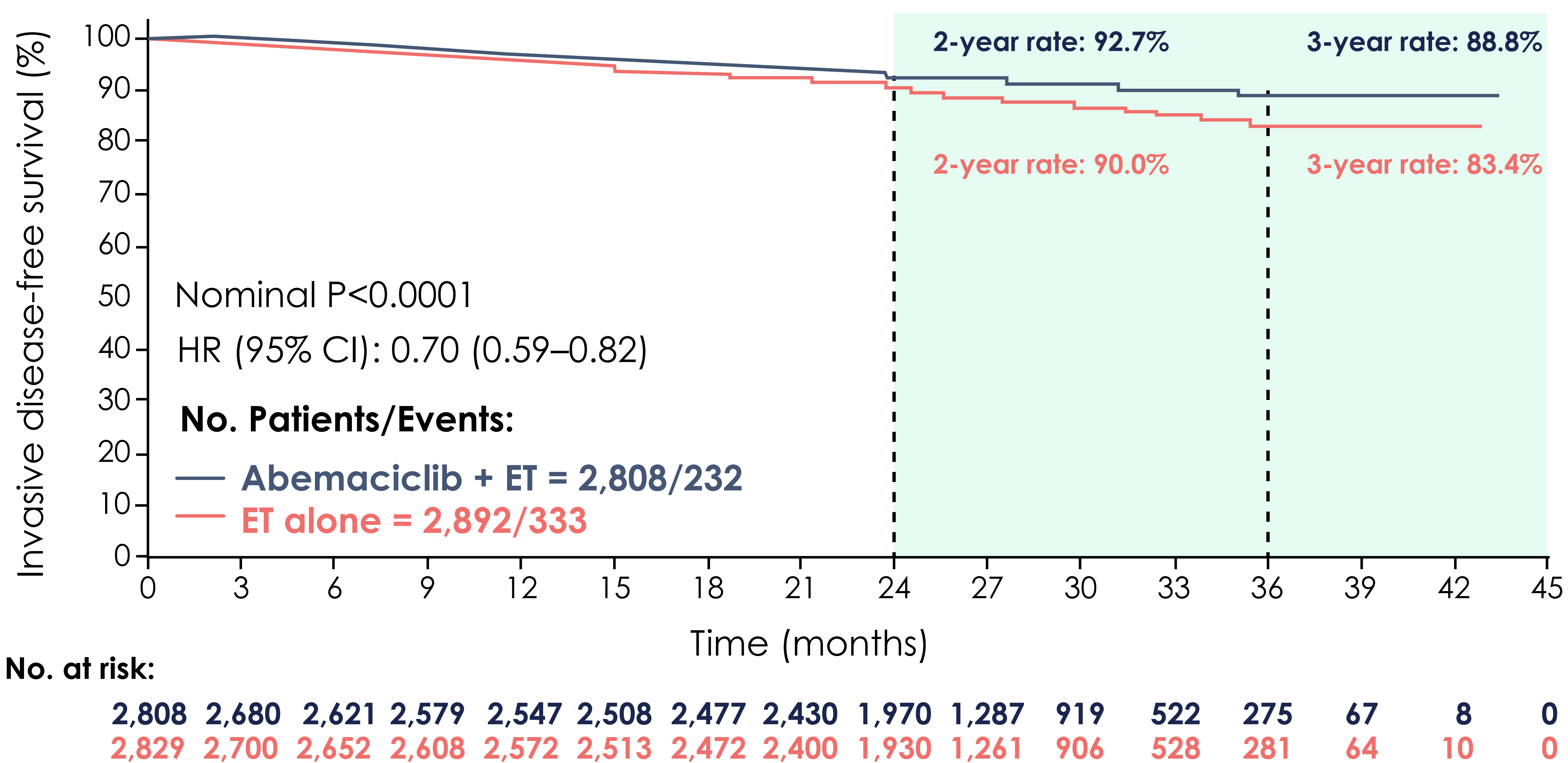
Results from the initial monarchE study showed¹

Abemaciclib + ET reduces metastatic recurrence risk by a clinically meaningful 29%, compared to **ET alone**

IDFS events were lower in the abemaciclib arm (4.8%) vs the control arm (6.6%), and with higher 2-year IDFS rates (92.2% vs 88.7%, respectively) (P=0.01)

Improvements were observed in DRFS after **abemaciclib + ET** treatment vs **ET alone** (P=0.01), with 2-year DRFS rates of 93.6% (abemaciclib) vs 90.3% (control)

Do the benefits observed in the initial monarchE study extend beyond the 2-year treatment period?



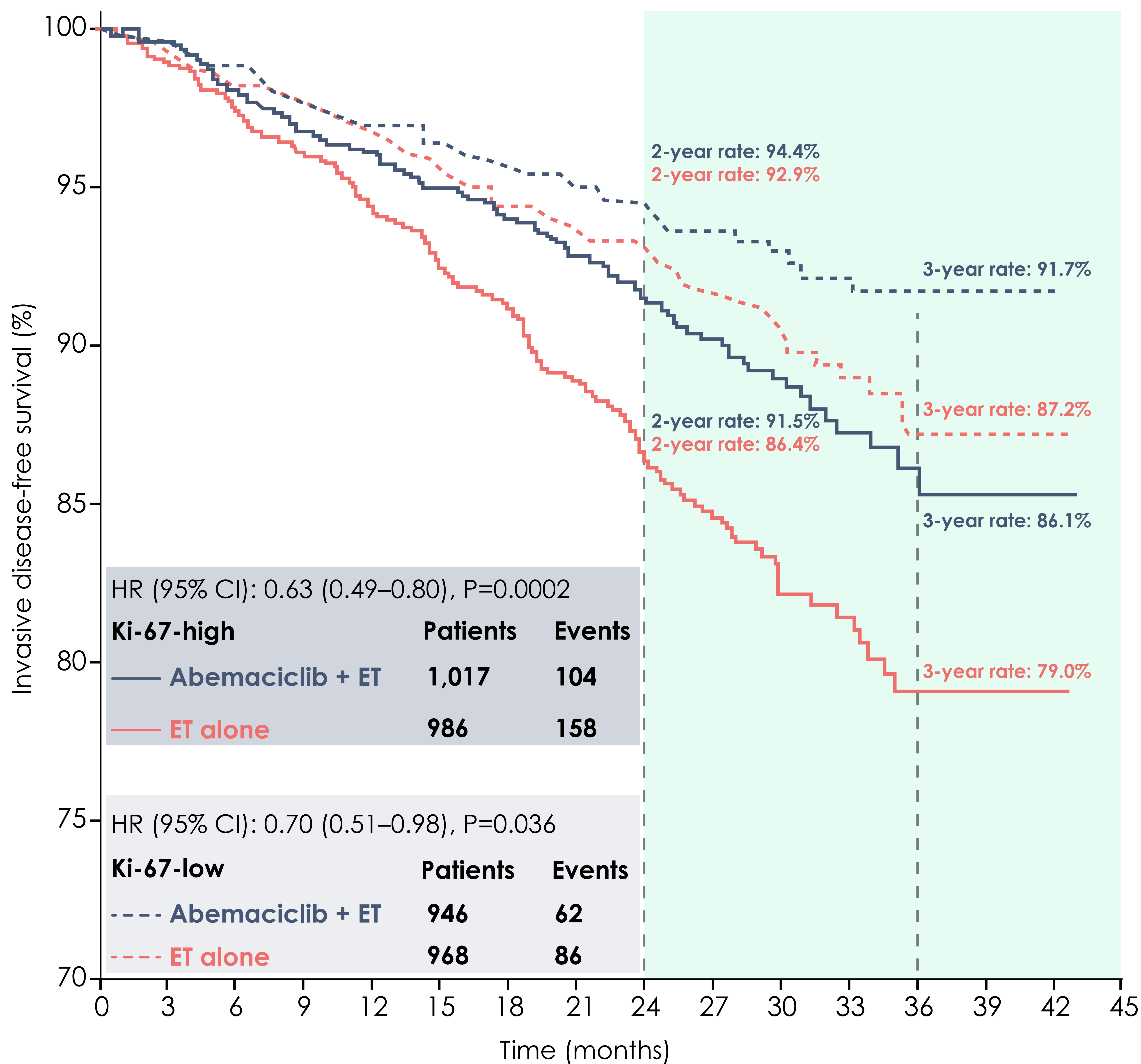
Key findings beyond the 2-year treatment period

Abemaciclib + ET resulted in a 29% reduction in the risk of IDFS at 19 months; this benefit extended beyond the 2-year treatment period

IDFS and DRFS benefit was maintained (P<0.0001) at 3-year follow-up, after 90% of patients had ceased abemaciclib treatment

Absolute improvements in 3-year IDFS, and DRFS rates, were 5.4% and 4.2% (P<0.0001)

Does Ki-67 index determine the efficacy of abemaciclib treatment for patients with HR+/HER2- EBC?



Adjuvant **abemaciclib + ET** benefited patients with high-risk clinicopathologic features, regardless of Ki-67 index

Ki-67 $\geq 20\%$ was prognostic, and may be used with clinicopathological features to identify patients at high risk of recurrence

Safety data were consistent with the known abemaciclib risk profile

CI, confidence interval; DRFS, distant relapse-free survival; EBC, early breast cancer; ET, endocrine therapy; HR, hazard ratio; HR+, hormone receptor positive; HER2-, human epidermal growth factor receptor 2 negative; IDFS, invasive disease-free survival.

Reference. 1. Johnston SRD, et al. Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer (monarchE). J Clin Oncol. 2020;38(34):3987–3998.

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