

Long-term efficacy of adjuvant abemaciclib + endocrine therapy (ET) in key subgroups in the monarchE trial



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OBJECTIVE

To present an updated efficacy analysis for key clinically relevant subgroups comprising age (≤40/>40 yrs), menopausal status (pre/post), prior chemotherapy (neoadjuvant/adjuvant), region (North America/Europe, Asia, other) in Cohort 1 of the monarchE trial.

CONCLUSIONS

In the monarchE trial for patients with node-positive, high-risk HR+, HER2- EBC, addition of 2 years of abemaciclib to ET showed clinically meaningful, sustained benefit across key clinically relevant subgroups in Cohort 1. Results were consistent in the ITT population.

- In the ET only arm, patients who were younger or received neoadjuvant chemotherapy had poorer prognosis among subgroups.
- Treatment benefit of abemaciclib in terms of IDFS, DRFS, and OS was consistently observed across all subgroups.

These data may inform clinical decisions and support adjuvant abemaciclib use in eligible patients, including those who were younger or received neoadjuvant chemotherapy, to reduce recurrence and mortality risk.

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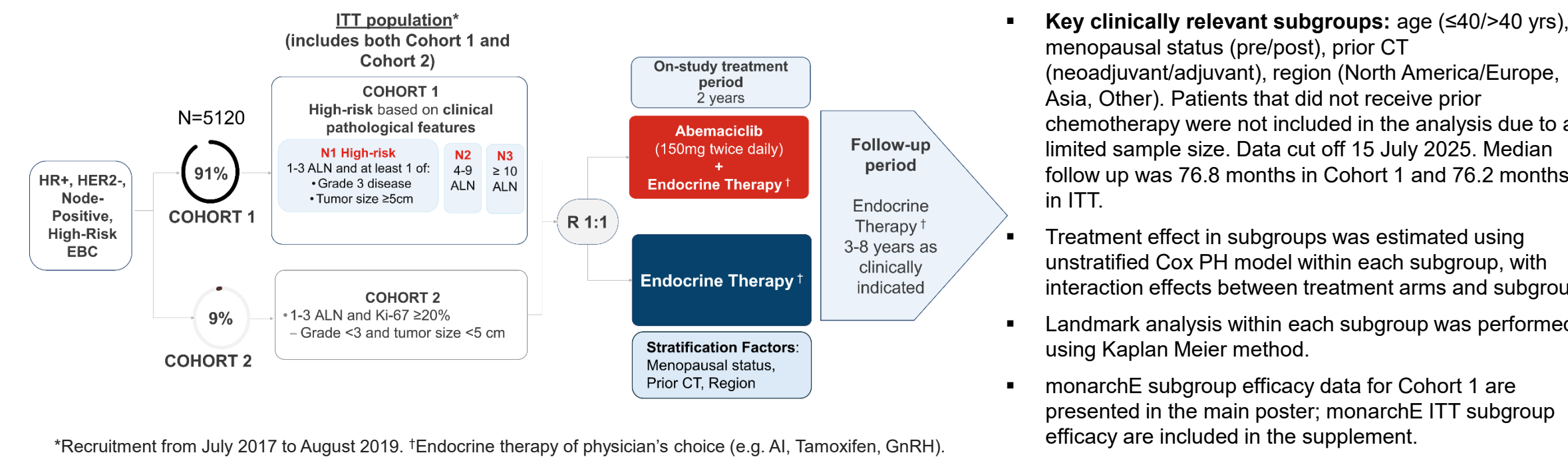
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BACKGROUND

- In monarchE, addition of 2 years of adjuvant abemaciclib to ET demonstrated statistically significant and clinically meaningful improvement over ET alone in invasive disease-free survival (IDFS) and overall survival (OS) in patients with HR+, HER2-, node-positive, high-risk early breast cancer (EBC).¹
- The monarchE Cohort 1 population represents 91% of patients and forms the basis of most global approvals.
- Previously, baseline characteristics of key clinically relevant subgroups have been described:
 - younger age:** patients who were younger (≤40 years) had a higher proportion of grade 3 tumors and NAC vs patients >40 years²
 - menopausal status:** patients who were premenopausal commonly had larger tumors and higher rate of neoadjuvant chemotherapy (NAC) use versus postmenopausal patients³
 - prior chemotherapy:** in addition to more commonly being premenopausal at baseline, patients who received NAC had larger tumors at baseline vs patients in the adjuvant chemotherapy subgroup⁴
 - geographic region:** patients in Asia were younger, predominantly pre-menopausal, and had a higher incidence of ≥4 lymph nodes⁵
- Treatment benefit of 2-year abemaciclib at longer follow-up time defined by these clinically relevant subgroups is highly important for adjuvant treatment of abemaciclib in high-risk EBC.

monarchE TRIAL DESIGN AND METHODS



*Recruitment from July 2017 to August 2019. †Endocrine therapy of physician's choice (e.g. AI, Tamoxifen, GnRH).

RESULTS

Consistent IDFS benefit across monarchE Cohort 1 key clinically relevant subgroups



- In the ET alone arm, higher risk of recurrence was seen in patients:
 - who were ≤40 years old (7-year IDFS rates of 65.5% vs 71.0% in >40 years group)
 - who received NAC (7-year IDFS rates of 61.3% vs 75.8% in the adjuvant chemotherapy only group)
- The treatment benefit of abemaciclib was consistently observed across all subgroups
- DRFS results are similar across key subgroups (DRFS KM curves are presented in the supplement).

Overall Survival

- OS results for the age analysis shows benefit across age groups with addition of abemaciclib to ET.
- Landmark analysis of OS rates was performed up to 6 years to ensure sufficient number of patients at risk in each subgroup.

Overall survival in monarchE Cohort 1 subgroup by age:

Events (n/N): ≤40y group abema + ET: 41/355 ET only: 58/399
 >40y group abema + ET: 245/2200 ET only: 286/2166

6Y OS rate: ≤40y group 89.6% vs 86.6% (Δ3.0%)
 >40y group 88.6% vs 87.3% (Δ1.3%)

HR (95% CI): ≤40y group 0.729 (0.488, 1.087) Interaction p-value 0.535
 >40y group 0.848 (0.715, 1.006)

- OS results for other subgroups have been previously published¹ and are consistent.

ABBREVIATIONS

Abbreviations: AI: aromatase inhibitor; ALN: axillary lymph nodes; Abema, abemaciclib; CT: chemotherapy; DRFS: distant relapse-free survival; EBC: Early Breast Cancer; ET: endocrine therapy; GnRH: gonadotropin-releasing hormone; HER2: human epidermal growth factor receptor 2 negative; HR: hazard ratio; HR+: hormone receptor positive; IDFS: invasive disease free-survival; ITT: Intent-to-treat population; KM: Kaplan Meier; NAC: neoadjuvant chemotherapy; OS: overall Survival; R: randomized.

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