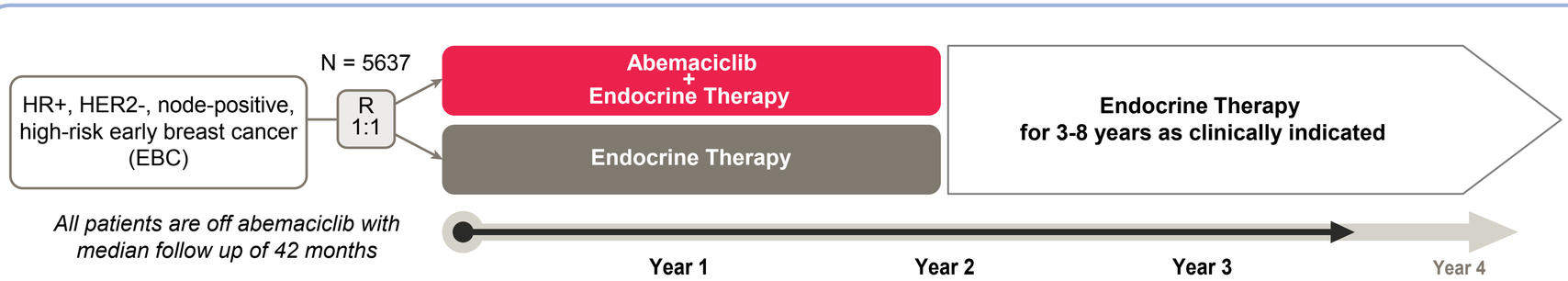
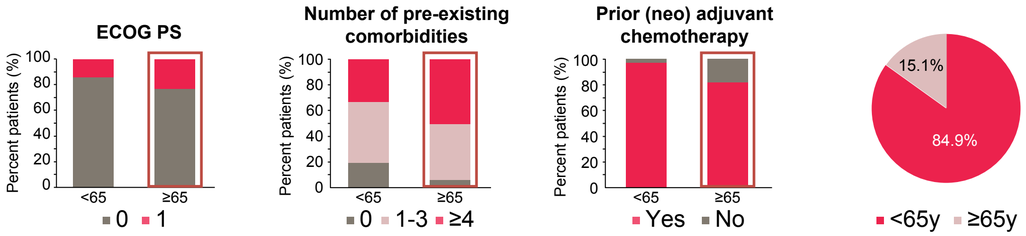
Adjuvant Abemaciclib + ET Showed Consistent Treatment Benefit, Similar Safety and Preserved QOL Across Age Subgroups in monarchE



Objective

Explore the efficacy and safety of adjuvant abemaciclib in the subgroup of older patients enrolled in monarchE

Older Patients Had More ECOG PS 1, More Pre-existing Comorbidities and Received Less Prior Chemotherapy

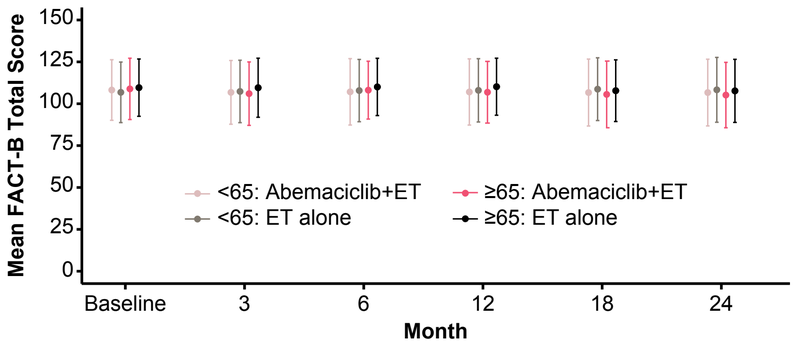


Older Patients Derive Similar Benefit from Abemaciclib as the ITT Population

	IDFS			DRFS		
	ITT	<65	≥65	ITT	<65	≥65
Events/N						
Abemaciclib + ET	336/2808	270/2371	66/437	281/2808	230/2371	51/437
ET alone	499/2829	414/2416	85/413	421/2829	353/2416	68/413
HR *(95% CI)*	**0.664** *(0.578, 0.762)*	**0.646** *(0.554, 0.753)*	**0.767** *(0.556, 1.059)*	**0.659** *(0.567, 0.767)*	**0.647** *(0.548, 0.764)*	**0.748** *(0.520, 1.077)*
Interaction p-value	**NA**		**0.35**	**NA**		**0.49**
4-year rate, % Absolute benefit	6.4	6.7	5.2	5.9	6.2	4.6

Consistent results observed in cohort 1

QOL was Similar Between Arms and Across Age Groups

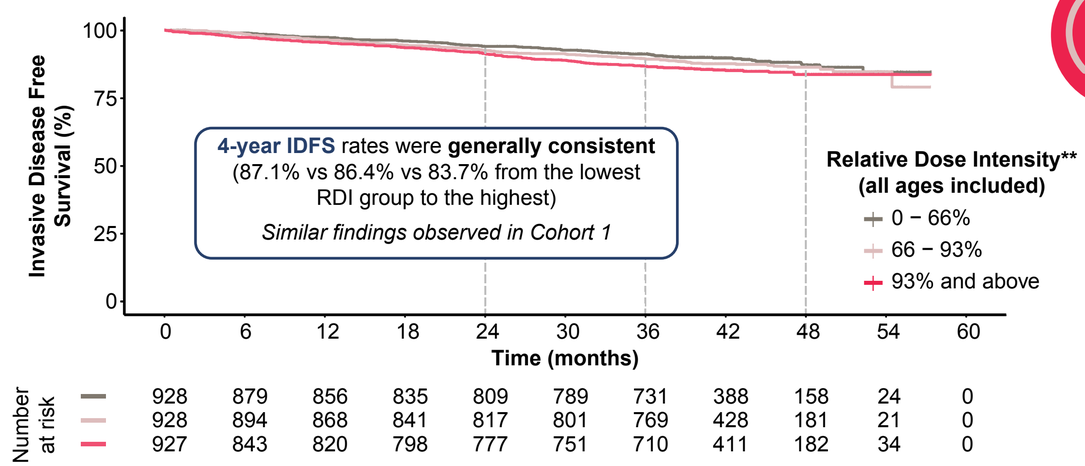


AE Rates were Similar Between Age Groups, but Dose Adjustments and Discontinuations were More Common in Older Patients

		Abemaciclib + ET		
		Overall, n=2791	<65, n=2361	≥65, n=430
Any AE, %	Any grade	98	98	99
	Grade ≥3	50	49	54
Clinically relevant AEs, %*				
Diarrhea	Grade 1	45	46	37
	Grade 2	31	31	30
	Grade 3	8	7	12
Fatigue	Grade 1	23	23	21
	Grade 2	15	14	20
	Grade 3	3	2	6
Neutropenia	Grade 1/2	26	27	22
	Grade ≥3	20	20	19
ALT increase	Grade 1/2	10	10	7
	Grade ≥3	3	3	3
Abemaciclib dose adjustments due to AEs, %				
Interruptions		62	60	68
Reductions		44	41	55
Discontinuations		18	15	38

Half of the patients in both groups discontinued abemaciclib without a prior dose reduction (<65y, 8%, ≥65y 19%).

Abemaciclib Benefit is Maintained when Dose Modifications are Undertaken to Manage AEs



Efficacy, safety and PRO results by age in monarchE **support the use of adjuvant abemaciclib in older patients**, and can be used to counsel patients about expectations of treatment experience.

References: ASCO 2023 Presentation. Hamilton E et al. Abstract #501. Efficacy and safety results by age in monarchE: Adjuvant abemaciclib combined with endocrine therapy (ET) in patients with HR+, HER2-, node-positive, high-risk early breast cancer (EBC).

Abbreviations: AE, adverse event; ALT, alanine transaminase; CI, confidence interval; DRFS, disease-free survival; EBC, early breast cancer; ECOG PS, Eastern Cooperative Oncology Performance Status; ET, endocrine therapy; FACT-B, Functional Assessment of Cancer Therapy - Breast; HER2-, human estrogen receptor 2-negative; HR, hormone receptor; HR+, hormone-receptor positive; IDFS, invasive disease-free survival; ILD, interstitial lung disease; ITT, intent-to-treat; PS, performance status; QOL, quality of life; R, randomized; RDI, relative dose intensity; VTE, venous thromboembolism.

*No differences between age subgroups in neutropenia, ALT increase, VTE and ILD rates were observed.** Dose adjustments result in lower relative dose intensity (RDI). RDI is defined as the average daily dose of abemaciclib received over the treatment duration, relative to the full dose (150mg BID). Patients treated with abemaciclib were classified into 3 equal sized subgroups according to their RDI, and IDFS rates were estimated within each subgroup.