THE ONLY CDK4/6 INHIBITOR WITH SIGNIFICANT IMPROVEMENT IN OS IN EARLY BREAST CANCER WITH HIGH RISK OF RECURRENCE*,a,2

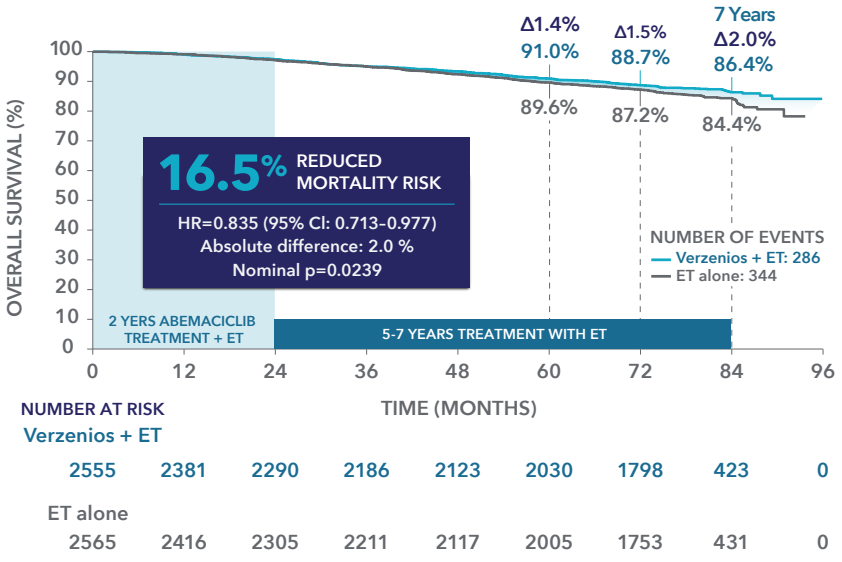
Verzenios® abemaciklib
A Lilly Medicine

HR+/HER2-, node-positive, early breast cancer with high risk of recurrence*

7-year follow-up in monarchE:

2 years of continuous treatment with Verzenios® (abemaciclib) + ET, compared with ET alone, prolongs overall survival (OS) and continues to reduce the risk of recurrence in invasive disease and distant recurrence[1,2]

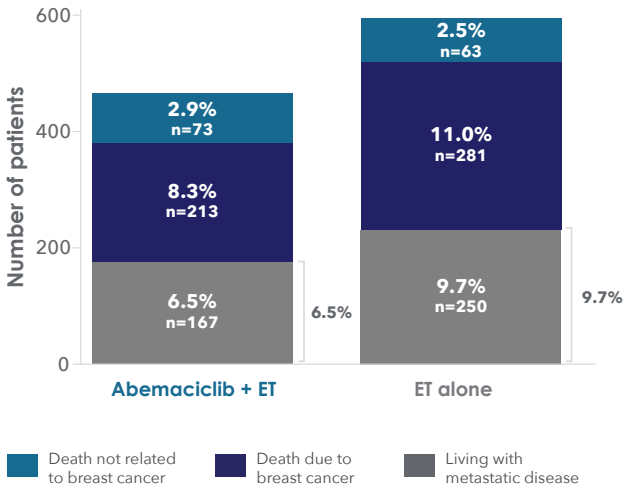
Prolongs overall survival (OS), Cohort 1, secondary endpoint[1,2]



NUMBER AT RISK

Verzenios + ET	2555	2381	2290	2186	2123	2030	1798	423	0
ET alone	2565	2416	2305	2211	2117	2005	1753	431	0

~30% fewer patients in the abemaciclib group were living with metastatic disease (DRFS), Cohort 1, secondary endpoint[1]



Graphs redrawn from graphs S5A and S9 in reference 1.

- **2 years of treatment with Verzenios + ET (AI or tamoxifen), compared with ET alone, reduced the risk of invasive disease recurrence by 27.4% at the 7-year follow-up** (primary endpoint, Cohort 1), HR=0.726 (95% KI:0.648-0.815). Absolute difference: 6.9%. Nominal p<0.0001.[1,2]
- **Approximately 30% fewer patients in the group receiving Verzenios + ET, compared with ET alone, were living with metastatic disease** (secondary endpoint)[1]
- **The longest median follow-up (6.3 years) reported for a CDK4/6 inhibitor in early breast cancer.[1,2]**
- **No new safety signals were reported; results were consistent with the previously known safety profile. Most adverse events could be managed with dose adjustment and/or dose interruption.[1-6]**

Read the full publication here

Verzenios (abemaciclib), Antineoplastic agents, protein kinase inhibitors, film-coated tablets 50, 100, 150 mg. Rx, F **Indications:** Early breast cancer: In combination with endocrine therapy, is indicated for the adjuvant treatment of adult patients with hormone receptor-positive (HR-positive), human epidermal growth factor receptor 2-negative (HER2-negative), node-positive early-stage breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinizing hormone-releasing hormone agonist (LHRH agonist). Advanced or metastatic breast cancer: For the treatment of women with HR-positive, HER2-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with an LHRH agonist. **Contraindications:** Hypersensitivity to any ingredient. **Warnings and precautions:** Neutropenia was reported. Infections have been reported in patients receiving abemaciclib together with endocrine therapy and should therefore be monitored for signs and symptoms. Venous thromboembolism and interstitial lung disease (ILD)/pneumonitis were reported; monitor patients for signs and symptoms and treat as medically appropriate. A potentially increased risk of serious arterial thromboembolic events (ATEs), including ischemic stroke and myocardial infarction, has been observed. Increases in ALT and AST were reported in patients receiving abemaciclib. Diarrhea is the most common adverse reaction and should be treated at the first sign. Concomitant use of CYP3A4 inducers should be avoided. **Fertility, pregnancy, breastfeeding:** Not recommended during pregnancy or in women of childbearing potential who are not using contraception. Women of childbearing potential should use highly effective contraception methods during treatment and for at least 3 weeks after completing therapy. Patients receiving abemaciclib should not breastfeed. **Date of revision of the SmPC:** 2026-08-25 **For further information and pricing, see** www.fass.se. Further information about this medicinal product can be obtained from the local representative of the marketing authorization holder: Eli Lilly Sweden AB, Box 721, 169 27 Solna. 08-737 88 00, www.lilly.com/se.

* High risk of recurrence in Cohort 1: Either ≥4 pALN (positive axillary lymph nodes), or 1–3 pALN and at least one of the following criteria: tumor size ≥5 cm or histological grade 3.

[a] 7-year follow-up in the monarchE study: Statistically significant improvement in OS in patients receiving Verzenios plus endocrine therapy compared with endocrine therapy alone within the ITT population. HR(95% CI): 0.842 (0.722, 0.981), absolute difference 1.8%, p=0.0273. Approval was obtained for the large subpopulation, Cohort 1, which comprised 91% of the ITT population.[2]

HR+= Hormone receptor; HER2-= Human epidermal growth factor receptor 2-negative; DRFS= Distant relapse-free survival; ET= Endocrine Therapy; AI= Aromatase inhibitor.

1. Johnston S et al Annals of Oncol 5 September 2025, Supplement. **2.** Verzenios Summary of Product Characteristics, www.fass.se, 08.2026. **3.** Rastogi P et al. J Clin Oncol. 2024;42(9):987-93. **4.** Johnston SRD et al. Lancet Oncol. 2023;24(1):77-90. **5.** Rugo HS et al. Ann Oncol. 2022;33(6):616-27. **6.** Goetz MP et al. NPJ Breast Cancer. 2024;10:34.

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