

Verzenio is the **FIRST** and **ONLY** CDK 4 & 6 inhibitor for people with HR+ HER2- node positive EBC at high-risk of recurrence.<sup>1-3</sup>

SHE NEEDS ALL THE  
*hope in the world*  
AND MORE

**4-year data  
in the EBC setting**

  
**Verzenio**<sup>™</sup>  
abemaciclib

**EARLY BREAST CANCER<sup>1</sup>**

Verzenio in combination with ET is indicated for the adjuvant treatment of adult patients with HR+, HER2-, node-positive EBC at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor ET should be combined with a LHRH agonist.

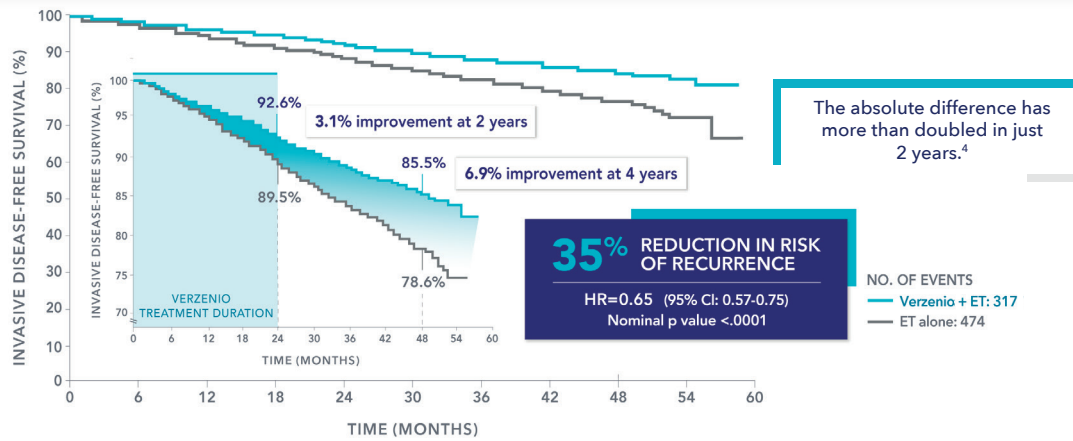
**ADVANCED OR METASTATIC BREAST CANCER<sup>1</sup>**

Verzenio is indicated for the treatment of women with HR+, HER2- 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 ET. In pre- or perimenopausal women, the ET should be combined with a LHRH agonist.

# 4-YEAR EFFICACY DATA FOR COHORT 1

The benefit of Verzenio + ET is sustained beyond the 2-year treatment period.<sup>4</sup>

The curves continue to separate with greater reduction in risk of recurrence beyond the 2-year Verzenio treatment period<sup>1,4</sup>

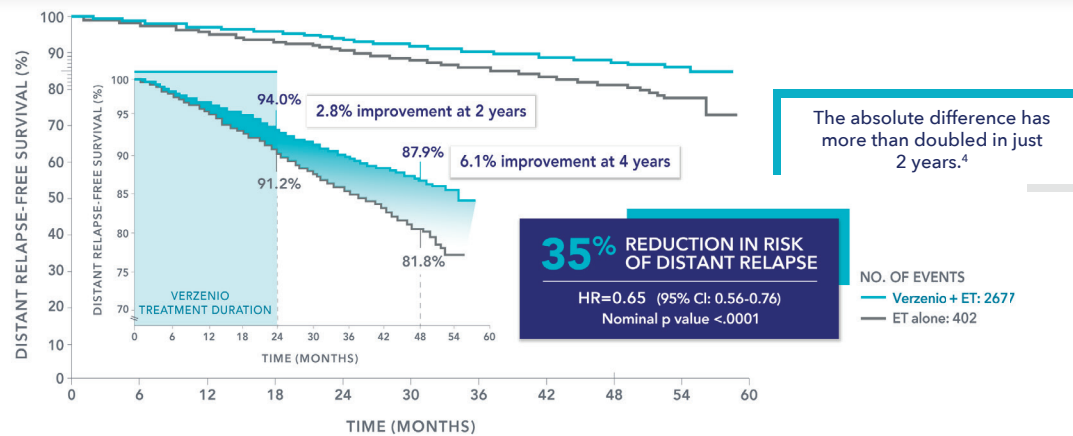


NUMBER AT RISK

|               | 0    | 6    | 12   | 18   | 24   | 30   | 36   | 42   | 48  | 54 | 60 |
|---------------|------|------|------|------|------|------|------|------|-----|----|----|
| Verzenio + ET | 2555 | 2387 | 2322 | 2256 | 2189 | 2129 | 2023 | 1162 | 520 | 79 | 0  |
| ET alone      | 2565 | 2404 | 2327 | 2236 | 2143 | 2059 | 1920 | 1134 | 511 | 82 | 0  |

- Efficacy analysis in Cohort 1 was not alpha controlled for statistical significance testing.
  - Statistical significance was met in the ITT population at the pre-planned interim analysis with 15.5 months median follow-up.<sup>1,5</sup>
- Absolute difference was calculated by subtraction of the IDFS rates between the two arms at each year. Results depicted in the KM curve should not be interpreted beyond 48 months.

The curves continue to separate with greater reduction in risk of metastatic disease beyond the 2-year Verzenio treatment period<sup>1,4</sup>



NUMBER AT RISK

|               | 0    | 6    | 12   | 18   | 24   | 30   | 36   | 42   | 48  | 54 | 60 |
|---------------|------|------|------|------|------|------|------|------|-----|----|----|
| Verzenio + ET | 2555 | 2396 | 2340 | 2275 | 2214 | 2156 | 2051 | 1183 | 534 | 81 | 0  |
| ET alone      | 2565 | 2411 | 2344 | 2259 | 2177 | 2102 | 1964 | 1162 | 525 | 85 | 0  |

- Efficacy analysis in Cohort 1 was not alpha controlled for statistical significance testing.
- Absolute difference was calculated by subtraction of the DRFS rates between the two arms each year. Results depicted in the KM curve should not be interpreted beyond 48 months.

monarchE enrolled 5,637 node-positive patients with a range of familiar high risk disease characteristics<sup>1,5</sup>

COHORT 1 (91% OF THE ITT POPULATION) WAS USED TO DEFINE THE EMA LABEL<sup>1,6</sup>

1 to 3 positive nodes AND tumor size ≥5 cm

OR

1 to 3 positive nodes AND histological grade 3

OR

≥4 positive nodes

# 4-YEAR SAFETY DATA

Safety remains consistent with prior analysis and known safety profile of Verzenio<sup>4</sup>

## Incidence of the most frequently reported AEs

|                    | Verzenio + ET<br>N = 2791, % |         |                | ET alone<br>N = 2800, % |         |                |
|--------------------|------------------------------|---------|----------------|-------------------------|---------|----------------|
|                    | Any grade                    | Grade 3 | Grade 4        | Any grade               | Grade 3 | Grade 4        |
| ≥20% in either arm |                              |         |                |                         |         |                |
| Diarrhea           | 83.6                         | 7.8     | 0 <sup>†</sup> | 8.7                     | 0.2     | 0              |
| Neutropenia        | 45.9                         | 19.0    | 0.7            | 5.6                     | 0.7     | 0.1            |
| Fatigue            | 40.8                         | 2.9     | 0 <sup>*</sup> | 18.0                    | 0.1     | 0 <sup>*</sup> |
| Leukopenia         | 37.7                         | 11.3    | 0.1            | 6.6                     | 0.4     | 0              |
| Abdominal pain     | 35.7                         | 1.4     | 0 <sup>*</sup> | 9.9                     | 0.3     | 0 <sup>*</sup> |
| Nausea             | 29.6                         | 0.5     | 0 <sup>*</sup> | 9.0                     | 0.1     | 0 <sup>*</sup> |
| Arthralgia         | 26.5                         | 0.3     | 0 <sup>*</sup> | 37.9                    | 1.0     | 0 <sup>*</sup> |
| Anemia             | 24.5                         | 2.0     | <0.1           | 3.9                     | 0.4     | <0.1           |
| Hot flush          | 15.4                         | 0.1     | 0 <sup>*</sup> | 23.0                    | 0.4     | 0 <sup>*</sup> |

<sup>†</sup>One Grade 5 event occurred. <sup>\*</sup>Max Grade 3 event (according to CTCAE v. 4).

## Dose modification is recommended based on individual safety and tolerability<sup>1</sup>

**DOSING<sup>1</sup>**  
Dose adjustment recommendations  
for adverse reactions

| Dose Level                     | Dose (in combination with ET) |
|--------------------------------|-------------------------------|
| Recommended dose               | 150 mg PO BID                 |
| 1 <sup>st</sup> dose reduction | 100 mg PO BID                 |
| 2 <sup>nd</sup> dose reduction | 50 mg PO BID                  |

**The majority of patients stayed on treatment<sup>‡</sup>**  
AEs were mainly low grade and manageable with comedication, dose adjustments, and/or dose hold.<sup>7</sup>

<sup>‡</sup>Discontinuation of Verzenio due to AEs occurred in 18.5% of the patients, mainly due to Grade 1/2 AEs<sup>7,8</sup>

## Most cases of diarrhea were low grade, early and transient<sup>1,5,7</sup>

**5.3%**

Discontinuation rate due to diarrhea was low (5.3%) - most cases could be managed with established protocols.<sup>1,7</sup>

**≤7 days**

Grade 2/3 events primarily occurred in the first 3 months, and most were short-lived (median duration ≤7 days) and did not recur.<sup>7</sup>

AE; Adverse Event, BID; Twice Daily, CDK4 & 6; Cyclin-Dependent Kinase 4 and 6, CI; Confidence Interval, CTCAE; Common Terminology Criteria for Adverse Events, DRFS; Distant Relapse-Free Survival, EBC; Early Breast Cancer, EMA; European Medicines Agency, ET; Endocrine Therapy, HER2; Human Epidermal Growth Factor Receptor 2, HR; Hazard Ratio, HR+; Hormone Receptor Positive, IDFS; Invasive Disease-Free Survival, ITT; Intention-to-Treat, KM; Kaplan Meier, LHRH; Luteinizing Hormone-Releasing Hormone, PO; By mouth.

1. Verzenio (pack insert). Singapore: Eli Lilly and Company. Date of revision of text: 10 Aug 2022. 2. Mayer EL et al. Lancet Oncol. 2021;22(2):212-22. 3. Clinical trials. Available at: <https://clinicaltrials.gov/ct2/show/NCT03701334>. [Accessed November 28th 2022]. 4. Johnston SRD et al. Lancet Oncol. 2022. Epub ahead of print. 5. Johnston SRD et al. J Clin Oncol. 2020;38(34):3987-98. 6. Toi M et al. The Oncologist. 2022. Epub ahead of print. 7. Rugo HS et al. Ann Oncol. 2022;33(6):616-27. 8. Johnston SRD et al. Poster presented at SABCS, San Antonio, USA, 6-10th Dec, 2022.



Before prescribing Verzenio (abemaciclib), please consult the full local prescribing information by scanning the following QR code.  
SAFETY REPORTING FOR POTENTIAL UNDESIRABLE EFFECTS:  
Please report adverse events to the DKSH Singapore Pte Ltd at [HEC-RA.Sin@dksh.com](mailto:HEC-RA.Sin@dksh.com)

For healthcare professionals only

  
**Verzenio™**  
abemaciclib

Market Expansion  
Services by  
[www.dksh.com](http://www.dksh.com)



**DKSH Singapore Pte Ltd**  
47 Jalan Buroh, #09-01, Singapore 619491  
Phone +65 6471 1466

VER/LB/270323/JL