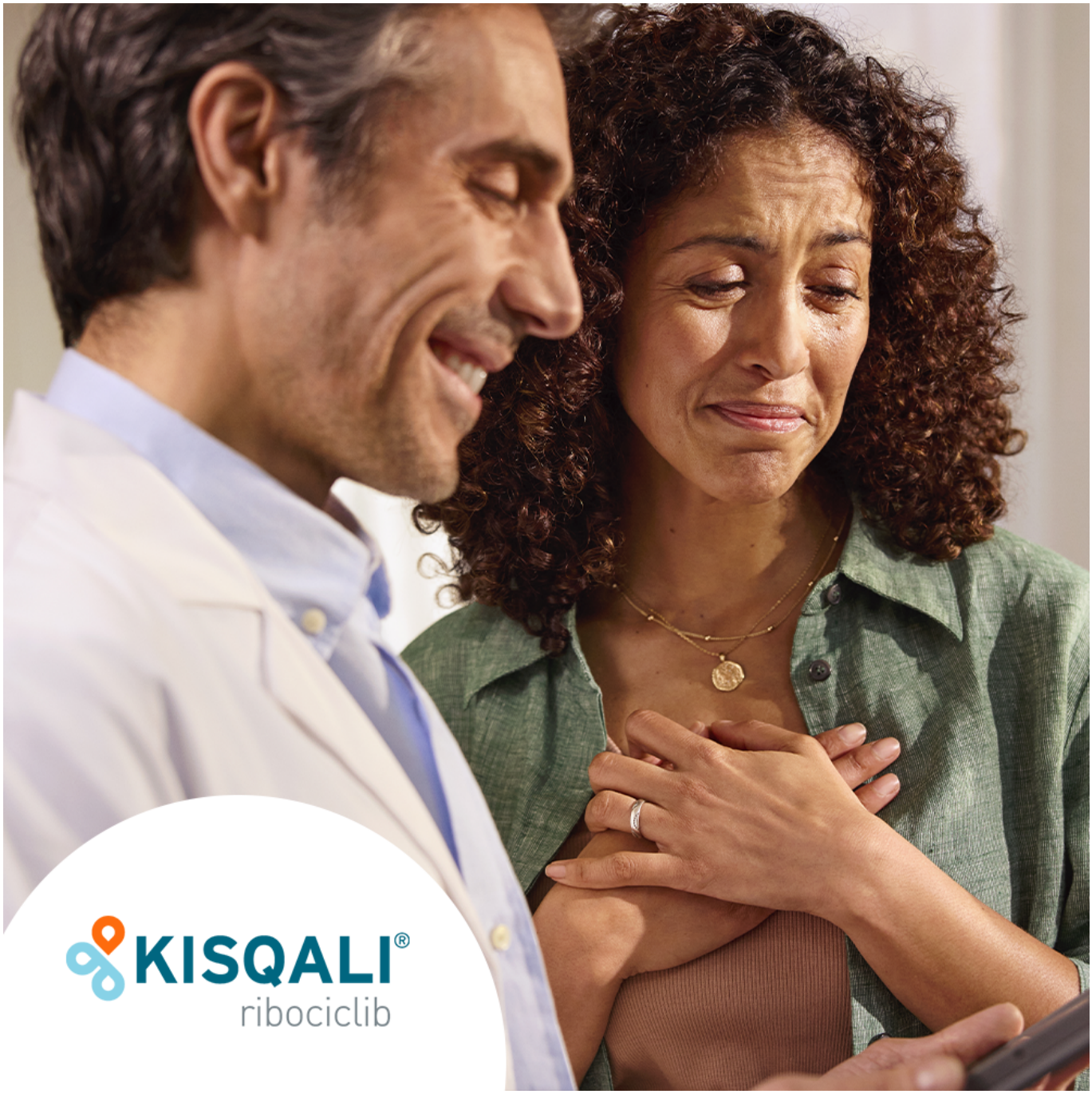
KISQALI - Pre- and perimenopausal women - HCP

Prescribing information

Image

Image



Treatment with KISQALI® (ribociclib) in eligible pre- and perimenopausal women with HR+/HER2− aBC

Indications:[1]

- KISQALI is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (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 a luteinising hormone-releasing hormone (LHRH) agonist

KISQALI is not recommended to be used in combination with tamoxifen.

To learn more about the safety profile of KISQALI, visit our portal page, here.

For full safety profile information, please refer to the Summary of Product Characteristics

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Typically, premenopausal women with aBC face a worse prognosis and more aggressive cancer compared to postmenopausal women[2,3]

Image

In an exploratory analysis, 1L KISQALI + ET* was observed to increase mOS by 11 months vs placebo + ET* in pre/perimenopausal patients[4]

This was an exploratory OS analysis for the NSAI subgroup with an extended follow-up of median 54 months.[4]

mOS at median 54-month follow-up was 58.7 months with KISQALI + AI vs 47.7 months with placebo + AI (HR=0.80; 95% CI: 0.62–1.04)[4]

Primary endpoint, PFS: At a median 19-month follow-up, mPFS in the overall population was 23.8 months (95% CI: 19.2–NR) in the KISQALI + ET* group versus 13.0 months (95% CI: 11.0–16.4) in the placebo + ET* group (HR=0.55, 95% CI: 0.44–0.69; p<0·0001)[5]

See below for MONALEESA-7 study design

*ET refers to AI + LHRH.[4]

Efficacy of KISQALI

Explore the efficacy data for KISQALI + ET in pre/perimenopausal patients from the MONALEESA-7 trial.

Click the start button to open the interactive detail aid in a new window.

START

Image

Click to learn about the efficacy of KISQALI + ET in postmenopausal patients with HR+/HER2- aBC

ET is defined as AI + LHRH or fulvestrant

Discover more

In HR+/HER2– aBC, KISQALI + ET is the only CDK4/6i with significant 1L OS benefit across three Phase III trials[4,6,7]

MONALEESA 2: mOS at median 80-month follow-up was 63.9 months with KISQALI + AI vs 51.4 months with AI alone (HR=0.76; 95% CI: 0.63–0.93; p=0.008). Analysis showed a significant and clinically meaningful increase in OS of 12.5 months with 1L KISQALI + AI vs placebo + AI in postmenopausal patients with HR+/HER2- aBC.[7]

MONALEESA-3: KISQALI + fulvestrant showed a significant OS benefit over placebo + fulvestrant. The estimated OS at 42-month follow-up was 57.8% (95% CI: 52.0–63.2) in the KISQALI group and 45.9% (95% CI: 36.9–54.5) in the placebo group, (HR=0.72; 95% CI: 0.57–0.92; p=0.00455).[6,8]

MONALEESA-7: The estimated OS at 42-month follow-up was 70.2% (95% CI: 63.5–76.0) in the KISQALI + ET group (n=335) and 46.0% (95% CI: 32.0–58.9) in the placebo + ET group (HR for death, 0.71; 95% CI: 0.54–0.95; p=0.00973 by log-rank test).[9]

Discover more on KISQALI safety profile

Click here

Explore QoL outcomes with KISQALI

Click here

Learn more about ESMO-MCBS and KISQALI

Click here

KISQALI is not recommended to be used in combination with tamoxifen.[1]

Summary of safety profile

The most common adverse reactions (ARs) (reported at a frequency ≥20%) in the pooled dataset for which the frequency for KISQALI plus any combination exceeds the frequency for placebo plus any combination were neutropenia, infections, nausea, fatigue, diarrhoea, leukopenia, vomiting, headache, constipation, alopecia, cough, rash, back pain, anaemia and abnormal liver function tests.[1]

For more safety information, click here.

Please consult your local Summary of Product Characteristics for the full KISQALI safety and tolerability profile.

Study design

MONALEESA-2: N=668, double-blind, placebo-controlled, 1:1 randomised, multicentre, phase III trial in postmenopausal women with HR+/HER2− aBC. As 1L in advanced disease. No prior ET for aBC and no previous systemic chemotherapy for advanced disease. KISQALI 600 mg or placebo orally once daily (3 weeks on/1 week off) + AI (letrozole 2.5 mg continuous). The primary endpoint was locally assessed PFS, and the key secondary endpoint was OS. Other secondary endpoints included the ORR (complete or partial response), the CBR (overall response plus stable disease lasting 24 weeks or more), safety, and QoL assessments.[10]

MONALEESA-3: N=726, double-blind, placebo-controlled, 2:1 randomised, phase III trial. As 1L and 2L in advanced disease plus those with early relapse in postmenopausal women with HR+/HER2– aBC. KISQALI 600 mg or placebo orally once daily (3 weeks on/1 week off) + 500 mg intramuscular fulvestrant. 1L defined as: newly diagnosed (*de novo*) aBC patients or patients with relapse >12 months from completion of (neo)adjuvant ET with no treatment for aBC or metastatic disease. 2L was defined as: relapse on or within 12 months from completion of (neo)adjuvant ET with no treatment for advanced or metastatic disease (early relapse); relapse >12 months from completion of (neo)adjuvant therapy with subsequent progression after one line of ET for advanced or metastatic disease, and advanced or metastatic breast cancer at diagnosis that progressed after one line of ET for advanced disease with no prior (neo)adjuvant treatment for early disease. The primary endpoint was locally assessed PFS. Secondary endpoints included OS, ORR, CBR, and safety and tolerability.[11]

MONALEESA-7: N=672, double-blind, placebo-controlled, 1:1 randomised, phase III trial in pre/perimenopausal women with HR+/HER2− aBC. As 1L in advanced disease and in patients who received 1 or fewer lines of chemotherapy for aBC. KISQALI 600 mg or placebo orally once daily (3 weeks on/1 week off) + ET (letrozole 2.5 mg or anastrozole 1 mg) or tamoxifen 20 mg orally once daily continuously + LHRH agonist (goserelin 3.6 mg subcutaneously on Day 1 of every cycle). The primary endpoint was investigator-assessed PFS. The key secondary endpoint was OS, defined as the time from randomisation to death from any cause.[9]

KISQALI is not recommended to be used in combination with tamoxifen.[1]

1L, first-line; 2L, second-line; aBC, advanced breast cancer; AI, aromatase inhibitor; AR, adverse reaction; CBR, clinical benefit rate; CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitor; CI, confidence interval; ESMO-MCBS, European Society for Medical Oncology magnitude of clinical benefit scale; ET, endocrine therapy; HER2−, human epidermal growth factor receptor 2-negative; HR, hazard ratio; HR+, hormone receptor-positive; LHRH, luteinising hormone-releasing hormone; mOS, median overall survival; mPFS, median progression-free survival; NR, not reached; NSAI, non-steroidal anti-inflammatory; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

References

1. KISQALI® (ribociclib) Summary of Product Characteristics.

2. Bardia A & Hurvitz S. *Clin Cancer Res* 2018;24(21):5206–5218.

3. Azim Jr HA & Partridge AH. *Breast Cancer Res* 2014;16:427.

4. Lu YS, et al. *Clin Cancer Res* 2022;28(5):851–859.

5. Tripathy MD, et al. *Lancet Oncol* 2018;19(7):904–915.

6. Neven P, et al. *Breast Cancer Res* 2023;25:103.

7. Hortobagyi GN et al. *N Engl J Med* 2022;386:942-950.

8. Slamon DJ, et al. *N Engl J Med* 2020;382(6):514–524.

9. Im SA, et al. *N Engl J Med* 2019;381(4):307–316.

10. Hortobagyi GN, et al. *N Engl J Med* 2016;375–1738–1748.

11. Slamon DJ, et al. *J Clin Oncol* 2018;36(24):2465–2472.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

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