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KISQALI - Efficacy of KISQALI - HCP

Prescribing information

Image

Image

Efficacy of KISQALI® (ribociclib)

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.

For more safety information, click here.

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

Is it time to make KISQALI your 1L CDK4/6i of choice for eligible HR+/HER2– aBC patients?[1]

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Increasing OS is a 1L key treatment goal for you and your patients with HR+/HER2– aBC, as reported in a physician and patient survey*[2]

In HR+/HER2– aBC, KISQALI + ET is the only CDK4/6i with significant 1L OS benefit across 3 Phase III trials[3-5]

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

- **MONALEESA-2:** At 80-months follow-up, a significant OS benefit was observed, with a mOS of 63.9 months (95% CI: 52.4–71.0) with KISQALI + AI (n=334) and 51.4 months (95% CI: 47.2–59.7) with placebo + AI (HR for death, 0.76; 95% CI: 0.63–0.93; two-sided p=0.008)[3]

- **MONALEESA-3:** KISQALI + fulvestrant (n=484) 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]

- **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)[7]

Results are from individual studies. They are presented together for illustrative purposes only and should not be directly compared. Due to the exploratory nature of some of the analyses, the statistics are descriptive and need to be interpreted with caution.

MONALEESA-2

Primary endpoint PFS: (n=334) In the primary and updated analyses, mPFS was significantly longer with KISQALI + AI than with placebo + AI (updated analysis: 25.3 months vs 16.0 months, respectively; HR for disease progression or death=0.57; 95% CI: 0.46–0.70, p<0.001).[3,8]

Image

1L KISQALI + AI increased mOS by >1 year (12.5 months) vs placebo + AI in postmenopausal patients[3]

- **Median follow-up of 80 months[3]**

Secondary endpoint:

At median follow-up of 80 months, mOS was 63.9 months (95% CI: 52.4–71.0) for KISQALI + AI and 51.4 months (95% CI: 47.2–59.7) for placebo + AI (HR for death, 0.76; 95% CI: 0.63–0.93, two-sided p=0.008)[3]

MONALEESA-3

Primary endpoint PFS: (n=484) KISQALI + fulvestrant showed a significant benefit in PFS versus placebo + fulvestrant with an mPFS of 20.5 months versus 12.8 months (HR=0.59; 95% CI: 0.48–0.73, p<0.001)[9]

Image

In an exploratory analysis, 1L KISQALI + fulvestrant was observed to demonstrate an increased OS rate vs fulvestrant + placebo in postmenopausal patients[4]

- **Extended median follow-up of 71 months[4]**

Exploratory endpoint:

At a median follow-up of 71 months, mOS was 67.6 months with 1L KISQALI + fulvestrant vs 51.8 months with placebo + fulvestrant (HR=0.67; 95% CI: 0.50–0.90).[4]

MONALEESA-7

Primary endpoint PFS: (n=335) KISQALI + ET (NSAI or tamoxifen plus goserelin) was associated with significant improvement in PFS versus placebo + ET (NSAI or tamoxifen plus goserelin), with a median of 23.8 months versus 13.0 months, respectively (HR=0.55; 95% CI: 0.44–0.69; p<0.001).[5,10]

Image

In an exploratory analysis, 1L KISQALI + ET was observed to increase mOS by 11 months vs placebo + ET in pre/perimenopausal patients[5]

- **Exploratory analysis for the NSAI subgroup with an extended median follow-up of 54 months[5]**
- **ET is defined as AI + LHRH**

Exploratory endpoint:

At a median follow-up of 54 months, mOS was 58.7 months with KISQALI + ET vs 47.7 months with placebo + ET (HR=0.80; 95% CI: 0.62–1.04).[5]

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

Click the links below to find out more about OS results in patients treated with KISQALI + ET:

Efficacy of KISQALI + ET in pre/perimenopausal patients with HR+/HER2– aBC

Efficacy of KISQALI + ET in pre/perimenopausal patients with HR+/HER2– aBC

See more details

Hide details

See below for MONALEESA-2, MONALEESA-3 and MONALEESA-7 study designs

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Summary of the 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]

Study designs

MONALEESA-2: Phase III trial of KISQALI + AI (n=334) vs placebo + AI (n=334) in postmenopausal patients with HR+/HER2– aBC. The primary endpoint was locally assessed PFS. OS was a key secondary endopoint. In the primary and updated analyses, mPFS was significantly longer with KISQALI + AI than with placebo + AI (updated analysis: 25.3 months vs 16.0 months; HR for disease progression or death=0.57; 95% CI: 0.46–0.70, p<0.001)[3,8]

MONALEESA-3: Phase III trial of KISQALI + fulvestrant (n=484) vs placebo + fulvestrant (n=242) in postmenopausal patients with HR+/HER2– aBC who were treatment naive or had received up to 1 line of prior ET in the advanced setting. The primary endpoint was locally assessed PFS. KISQALI + fulvestrant showed a significant benefit in PFS versus placebo + fulvestrant with an mPFS of 20.5 versus 12.8 months (HR=0.59; 95% CI: 0.48–0.73, p<0.001). OS was a secondary endpoint.[9]

MONALEESA-7: Phase III trial of KISQALI + ET (NSAI or tamoxifen) (n=335) vs placebo + ET (NSAI or tamoxifen) (n=337) in pre- and perimenopausal patients with HR+/HER2– aBC. The primary endpoint was investigator-assessed PFS. KISQALI was associated with a significant improvement in PFS, with a median of 23.8 vs 13.0 months with placebo (HR=0.55; 95% CI: 0.44–0.69, p<0.001). The key secondary endpoint was OS.[5,10]

*Quantitative and qualitative primary research with more than 500 respondents (including 392 physicians managing metastatic breast cancer patients and patients themselves). Top reported goals included OS and maintaining day to day activities.[2]

1L, first-line; 2L, second-line; aBC, advanced breast cancer; CDK4/6, cyclin-dependent kinase 4 and 6; CI, confidence interval; 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; NSAI, non-steroidal aromatase inhibitor; OS, overall survival; PFS, progression-free survival.

References

1. KISQALI (ribociclib) Summary of Product Characteristics.

2. Pfizer Oncology. Meaningful Goals in the Management of mBC. 2017. Available at: https://www.breastcancervision.com/sites/default/files/section-pdf/mbc_goals-whitepaper_final_with_date.pdf [Accessed February 2025].

3. Hortobagyi GN, et al. *N Engl J Med* 2022;386(10):942–950.

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

5. Lu Y-S, et al. *Clin Cancer Res* 2022;28:851–859.

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

7. Im S-A, et al. *N Engl J Med* 2019;381(4):307–316.

8. Hortobagyi GN, et al. *Ann Oncol* 2018;29:1541–1547.

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

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