KISQALI—doubled mPFS vs combination chemotherapy in 1L patients with HR+/HER2- mBC who have aggressive disease

NCCN CATEGORY 1

National Comprehensive Cancer Network® (NCCN®) **differentiates ribociclib (KISQALI®) as the only Category 1 Preferred 1L treatment option** in combination with an AI for appropriate patients with HR+/HER2- mBC[1]

There is controversy on the choice of CDK4/6 inhibitor as there are no head-to-head comparisons between the agents and there are some differences in the study populations in the phase III randomized studies.

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MONALEESA-2, statistically significant overall survival in 1L postmenopausal patients: At a median follow-up of 80 months, median OS was 63.9 months with KISQALI + letrozole (95% CI: 52.4-71.0) vs 51.4 months with letrozole (95% CI: 47.2-59.7); HR=0.765 (95% CI: 0.628-0.932); *P*=0.004. PFS was the primary end point.

RIGHT Choice: Efficacy results are from a subgroup analysis of patients with aggressive disease who did not have visceral crisis. In this subgroup, median PFS was 24.0 months with KISQALI + AI + goserelin (95% CI: 21.1-NE) vs 12.8 months with combination chemotherapy (95% CI: 8.5-17.5); HR=0.42 (95% CI: 0.25-0.70). Due to the nature of the study, results should be interpreted with caution. These results are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.

Aggressive disease is characterized by rapidly growing cancer cells that are more likely to spread (metastasize) to other parts of the body. Aggressive breast cancer is generally associated with a higher risk of recurrence and poorer prognosis.

Indications

KISQALI is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

- an aromatase inhibitor as initial endocrine-based therapy; or
- fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

IMPORTANT SAFETY INFORMATION

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

Across clinical trials in patients with advanced or metastatic breast cancer treated with KISQALI in combination with an aromatase inhibitor or fulvestrant (“KISQALI treatment groups”), 1.6% of patients treated with KISQALI had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have been observed in the postmarketing setting, with fatalities reported.

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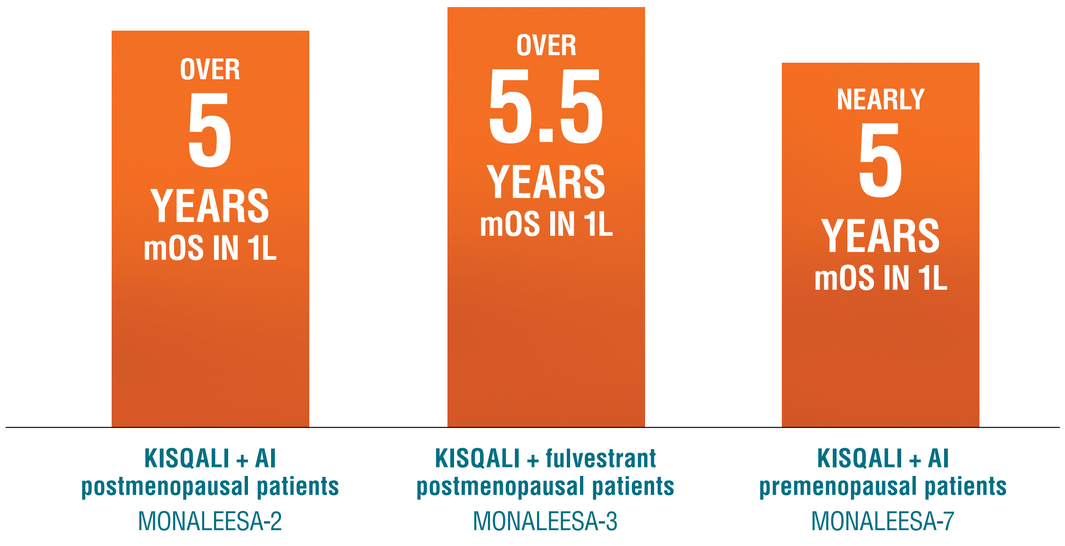
KISQALI—the only CDK4/6 inhibitor to achieve statistically significant overall survival in a broad range of patients across 3 phase III trials



1L refers to patients with mBC across all trials

MONALEESA-2 was a randomized, double-blind, placebo-controlled, phase III study of KISQALI 600 mg (dosed orally, once daily for the first 21 days followed by 7 days off, resulting in a complete cycle of 28 days) + letrozole (n=334) vs placebo + letrozole (n=334) in postmenopausal patients with HR+/HER2- mBC who received no prior therapy for advanced disease. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 80 months, mOS was 63.9 months with KISQALI + letrozole (95% CI: 52.4-71.0) vs 51.4 months with placebo + letrozole (95% CI: 47.2-59.7); HR=0.765 (95% CI: 0.628-0.932); *P*=0.004.[2-4]

MONALEESA-3 was a randomized, double-blind, placebo-controlled, phase III study of KISQALI 600 mg (dosed orally, once daily for the first 21 days followed by 7 days off, resulting in a complete cycle of 28 days) + fulvestrant (n=484) vs placebo + fulvestrant (n=242) in postmenopausal patients with HR+/HER2- mBC who have received no or only 1 line of prior ET for advanced disease. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 71 months (exploratory analysis), in a 1L subgroup analysis, mOS was 67.6 months (95% CI: 59.6-NR) with KISQALI + fulvestrant vs 51.8 months with placebo + fulvestrant (95% CI: 40.4-61.2); HR=0.673 (95% CI: 0.504-0.899). At a median follow-up of 39 months, statistical significance was established for overall survival in the ITT population; HR=0.724 (95% CI: 0.568-0.924); *P*=0.00455. Results from the 71-month analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error.[2,5-7]

MONALEESA-7 was a randomized, double-blind, placebo-controlled, phase III study of KISQALI 600 mg (dosed orally, once daily for the first 21 days followed by 7 days off, resulting in a complete cycle of 28 days) + ET (NSAI or tamoxifen) + goserelin (n=335) vs placebo + ET (NSAI or tamoxifen) + goserelin (n=337) (ITT) in premenopausal patients with HR+/HER2- mBC who received no prior ET for advanced disease. **KISQALI is not indicated for concomitant use with tamoxifen.** Efficacy results are from a prespecified subgroup analysis of 495 patients who received KISQALI (n=248) or placebo (n=247) with an NSAI + goserelin and were not powered to show statistical significance. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 54 months (exploratory analysis), mOS was 58.7 months with KISQALI + NSAI + goserelin (95% CI: 48.5-NR) vs 47.7 months with placebo + NSAI + goserelin (95% CI: 41.2-55.4); HR=0.798 (95% CI: 0.615-1.035). At a median follow-up of 35 months, statistical significance was established for overall survival in the ITT population; HR=0.71 (95% CI: 0.54-0.95); *P*=0.00973. Results from the 54-month analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error.[2,8-11]

IMPORTANT SAFETY INFORMATION (continued)

Interstitial lung disease/pneumonitis (continued). Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt treatment with KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with recurrent symptomatic or severe ILD/pneumonitis.

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KISQALI + AI + goserelin was studied in patients with aggressive disease

RIGHT Choice trial

Study design[12-14]

- Randomized, phase II, open-label, multicenter trial
- Primary end point: PFS
- Select secondary end points: OS and ORR
- Treatment arms
  - KISQALI + AI (letrozole or anastrozole) + goserelin (n=112)
  - Combination chemotherapy (either of docetaxel + capecitabine, paclitaxel + gemcitabine, or capecitabine + vinorelbine) (n=110)
  - As determined by the investigators, 106 patients presented with visceral crisis and 116 patients presented without visceral crisis
  - Visceral crisis, defined subjectively as severe organ dysfunction, as assessed by signs and symptoms, laboratory studies, and rapid progression of the disease, in patients with mBC often requires a treatment with rapid efficacy

Key inclusion criteria[12,15]

- Pre-/perimenopausal patients with HR+/HER2- mBC who received no prior systemic therapy for advanced disease
- >10% ER+
- Patients must have met at least 1 of the following criteria, for which combination chemotherapy was clinically indicated:
  - Symptomatic visceral metastases
  - Markedly symptomatic nonvisceral disease if the treating physician opted to give chemotherapy for rapid palliation of patients' symptoms
  - Rapid progression of disease or impending visceral compromise

RIGHT CHOICE: SELECT BASELINE CHARACTERISTICS[12]

Characteristic	KISQALI + AI + goserelin (n=112)	Combination chemotherapy (n=110)
Median age, years	44	43
De novo disease	63%	66%
Aggressive disease characteristics		
Symptomatic visceral metastases	66%	69%
Rapid progression	21%	16%
Symptomatic nonvisceral disease	13%	15%
Metastatic sites		
Liver	48%	48%
Lung	55%	50%
Liver or lung	78%	75%

IMPORTANT SAFETY INFORMATION (continued)

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

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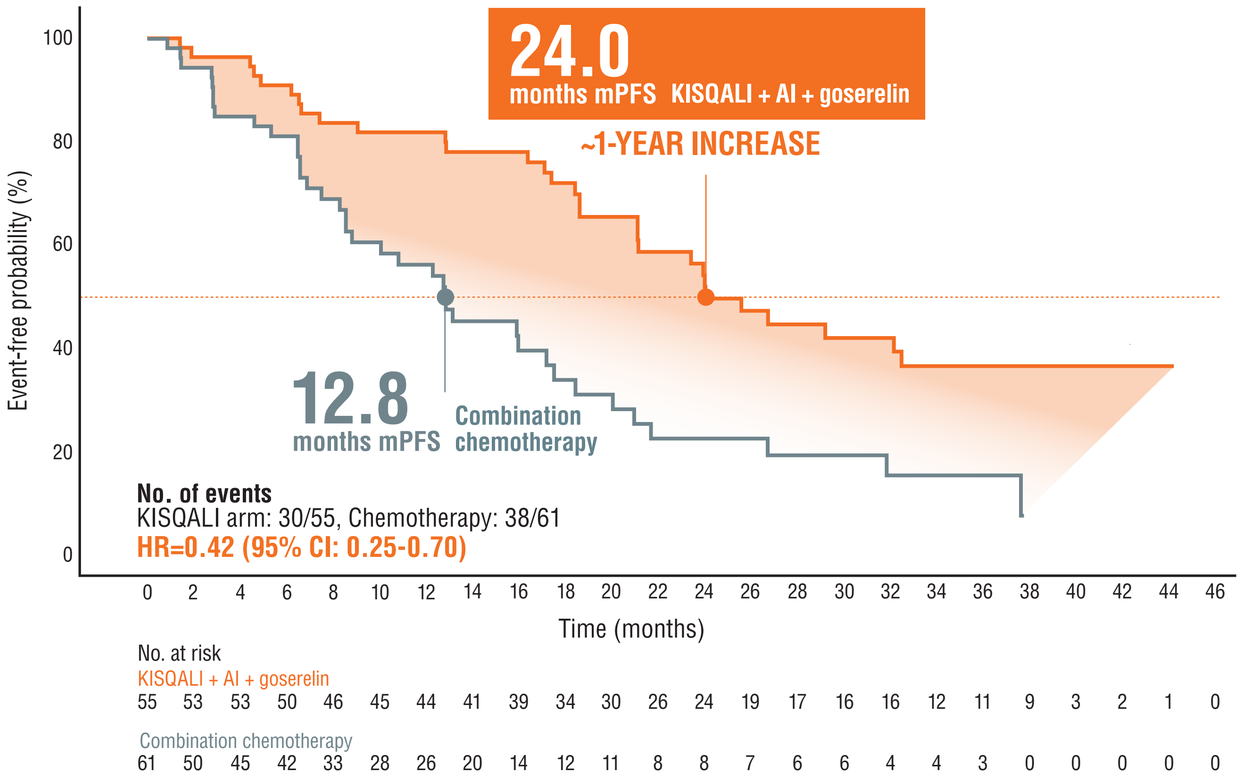
KISQALI + AI + goserelin vs combination chemotherapy in aggressive HR+/HER2- advanced breast cancer: subgroup analysis of patients without visceral crisis

The RIGHT Choice trial: a phase II trial evaluating KISQALI + an AI + goserelin for 1L treatment of pre- or perimenopausal patients with HR+/HER2- mBC who have aggressive disease[12]

MEDIAN PFS | KISQALI + AI + GOSERELIN SUBGROUP WITHOUT VISCERAL CRISIS[16]



Overall survival is being evaluated, but is ongoing and currently not yet mature.[13]

KISQALI + AI + goserelin tumor response rates were consistent with combination chemotherapy[12,16]

- KISQALI + AI + goserelin ORR: 60.0% (95% CI: 45.9-73.0)
- Combination chemotherapy ORR: 62.3% (95% CI: 49.0-74.4)

Due to the nature of the study, results should be interpreted with caution. These results from a subgroup analysis of patients with aggressive disease who did not have visceral crisis are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.

IMPORTANT SAFETY INFORMATION (continued)

Severe cutaneous adverse reactions (continued). If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended.

If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

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KISQALI demonstrated >5 years median overall survival in 1L patients with visceral disease across 3 phase III MONALEESA trials

In an exploratory, pooled subgroup analysis of 1L patients with visceral metastases (n=709) from MONALEESA-2, -3, and -7:

KISQALI increased median OS by 1 year in 1L pre- and postmenopausal patients with visceral metastases[17]

At a median follow-up of 72 months

63.4
MONTHS mOS

KISQALI + ET
vs 51.8 months with placebo + ET;
HR=0.78 (95% CI: 0.64-0.96)
22% REDUCTION IN RISK OF DEATH[17]

1L patients were defined as those with de novo disease (no prior exposure to ET) and those with relapse >12 months from the end of (neo)adjuvant ET (late relapse).

PATIENTS IN THE EXPLORATORY POOLED SUBGROUP ANALYSIS[4,5,8,17]

	KISQALI	Placebo
Total patients included from the MONALEESA trials	1066	823
Patients with visceral metastases	640	484
Patients with visceral metastases receiving 1L therapy	392	317

This pooled analysis included 1889 patients from across the MONALEESA trials, of which 59.5% (n=1124) had visceral metastases; of the 1229 patients receiving 1L therapy, 57.7% (n=709) had visceral metastases.[17]

These results are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation. Across KISQALI treatment groups, 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms increase from baseline in QTcF intervals. These electrocardiogram (ECG) changes were reversible with dose interruption and most occurred within the first 4 weeks of treatment. No cases of torsades de pointes were reported. In MONALEESA-2, on the KISQALI + letrozole treatment arm, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation. No cases of sudden death were reported in MONALEESA-7 or MONALEESA-3.

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Important Safety Information (continued)

QT interval prolongation (continued). Assess ECG prior to initiation of treatment. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, at the beginning of the second cycle, and as clinically indicated. Monitor serum electrolytes (including potassium, calcium, phosphorus, and magnesium) prior to the initiation of treatment, at the beginning of each of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting therapy with KISQALI.

Avoid the use of KISQALI in patients who already have or who are at significant risk of developing QT prolongation, including patients with:

- long QT syndrome
- uncontrolled or significant cardiac disease including recent myocardial infarction, congestive heart failure, unstable angina, and bradyarrhythmias
- electrolyte abnormalities

Avoid using KISQALI with drugs known to prolong the QT interval and/or strong CYP3A inhibitors, as this may lead to prolongation of the QTcF interval.

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. In MONALEESA-7, the observed mean QTcF increase from baseline was ≥10 ms higher in the tamoxifen + placebo subgroup compared with the non-steroidal aromatase inhibitor (NSAI) + placebo subgroup. In the placebo arm, an increase of >60 ms from baseline occurred in 6/90 (7%) of patients receiving tamoxifen, and in no patients receiving an NSAI. An increase of >60 ms from baseline in the QTcF interval was observed in 14/87 (16%) of patients in the KISQALI and tamoxifen combination and in 18/245 (7%) of patients receiving KISQALI plus an NSAI.

Hepatobiliary toxicity. Across KISQALI treatment groups, increases in transaminases were observed. Across all trials, grade 3/4 increases in alanine aminotransferase (ALT) (11% vs 2.1%) and aspartate aminotransferase (AST) (8% vs 2%) were reported in the KISQALI and placebo arms, respectively.

Among the patients who had grade ≥3 ALT/AST elevation, the median time to onset was 92 days and median time to resolution to grade ≤2 was 21 days for the KISQALI treatment groups.

In MONALEESA-2 and MONALEESA-3, concurrent elevations in ALT or AST greater than 3 times the upper limit of normal (ULN) and total bilirubin greater than 2 times the ULN, with normal alkaline phosphatase, in the absence of cholestasis occurred in 6 (1%) patients and all patients recovered after discontinuation of KISQALI. No cases occurred in MONALEESA-7.

Hepatobiliary toxicity (continued). Perform liver function tests (LFTs) before initiating therapy with KISQALI. Monitor LFTs every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation. Recommendations for patients who have elevated AST/ALT grade ≥3 at baseline have not been established.

Neutropenia. Across KISQALI treatment groups neutropenia was the most frequently reported adverse reaction (AR) (75%), and a grade 3/4 decrease in neutrophil count (based on laboratory findings) was reported in 62% of patients in the KISQALI treatment groups. Among the patients who had grade 2, 3, or 4 neutropenia, the median time to grade ≥2 was 17 days. The median time to resolution of grade ≥3 (to normalization or grade <3) was 12 days in the KISQALI treatment groups. Febrile neutropenia was reported in 1.7% of patients in the KISQALI treatment groups. Treatment discontinuation due to neutropenia was 1%.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction, or discontinuation.

Embryo-fetal toxicity. Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of KISQALI to pregnant rats and rabbits during organogenesis caused embryo-fetal toxicities at maternal exposures that were 0.6 and 1.5 times the human clinical exposure, respectively, based on area under the curve. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose.

Adverse reactions. Most common (incidence ≥20%) adverse reactions include infections, nausea, fatigue, diarrhea, vomiting, headache, constipation, alopecia, cough, rash, and back pain.

Laboratory abnormalities. Across clinical trials of patients with advanced or metastatic breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, AST increased, gamma-glutamyl transferase increased, ALT increased, creatinine increased, platelets decreased, and glucose serum decreased.**

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References

1L=first line; AI=aromatase inhibitor; CDK=cyclin-dependent kinase; ER+=estrogen receptor-positive; ET=endocrine therapy; HR=hazard ratio; ITT=intent to treat; mBC=metastatic breast cancer; mOS=median overall survival; mPFS=median progression-free survival; NE=not estimable; NR=not reached; NSAI=nonsteroidal aromatase inhibitor; ORR=overall response rate; OS=overall survival; PFS=progression-free survival.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 17, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Kisqali. Prescribing information. Novartis Pharmaceuticals Corp. **3.** Hortobagyi GN, Stemmer SM, Burris HA, et al. Overall survival with ribociclib plus letrozole in advanced breast cancer. *N Engl J Med.* 2022;386(10):942-950. doi:10.1056/NEJMoa2114663 **4.** Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. *N Engl J Med.* 2016;375(18):1738-1748. doi:10.1056/NEJMoa1609709 **5.** Slamon DJ, Neven P, Chia S, et al. Phase III randomized study of ribociclib and fulvestrant in hormone receptor–positive, human epidermal growth factor receptor 2–negative advanced breast cancer: MONALEESA-3. *J Clin Oncol.* 2018;36(24):2465-2472. doi:10.1200/JCO.2018.78.9909 **6.** Neven P, Fasching PA, Chia S, et al. Updated overall survival from the MONALEESA-3 trial in postmenopausal women with HR+/HER2– advanced breast cancer receiving first-line ribociclib plus fulvestrant. *Breast Cancer Res.* 2022;28(5):851-859. doi:10.1158/1078-0432.CCR-21-3032 **7.** Slamon DJ, Neven P, Chia S, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. *N Engl J Med.* 2020;382(6):514-524. doi:10.1056/NEJMoa1911149 **8.** Tripathy D, Im S-A, Colleoni M, et al. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial. *Lancet Oncol.* 2018;19(7):904-915. doi:10.1016/S1470-2045(18)30292-4 **9.** Lu YS, Im SA, Colleoni M, et al. Updated overall survival of ribociclib plus endocrine therapy versus endocrine therapy alone in pre- and perimenopausal patients with HR+/HER2- advanced breast cancer in MONALEESA-7: a phase III randomized clinical trial. *Clin Cancer Res.* 2022;28(5):851-859. doi:10.1158/1078-0432.CCR-21-3032 **10.** Data on file. CLEE011E2301. Novartis Pharmaceuticals Corp; 2020. **11.** Im S-A, Lu Y-S, Bardia A, et al. Overall survival with ribociclib plus endocrine therapy in breast cancer. *N Engl J Med.* 2019;381(4):307-316. doi:10.1056/NEJMoa1903765 **12.** Azim H, El Saghir NS, Yap Y-S, et al. First-line ribociclib + endocrine therapy vs combination chemotherapy in aggressive HR+/HER2– advanced breast cancer: a subgroup analysis of patients with or without visceral crisis from the phase II RIGHT Choice study. Poster presented at: ESMO Congress 2023; October 20-24, 2023; Madrid, Spain, and virtual. Poster 402P. **13.** Lu Y-S, Mahidin EIBM, Azim H, et al. Primary results from the randomized phase II RIGHT Choice trial of premenopausal patients with aggressive HR+/HER2– advanced breast cancer treated with ribociclib + endocrine therapy vs physician's choice combination chemotherapy. Presented at: San Antonio Breast Cancer Symposium 2022; December 6-10, 2022; San Antonio, TX. Abstract GS1-10. **14.** Cardoso F, Paluch-Shimon S, Senkus E, et al. 5th ESO-ESMO international consensus guidelines for advanced breast cancer (ABC 5). *Ann Oncol.* 2020;31(12):1623-1649. doi:10.1016/j.annonc.2020.09.010 **15.** Study to compare the combination of ribociclib plus goserelin acetate with hormonal therapy versus combination chemotherapy in premenopausal or perimenopausal patients with advanced or metastatic breast cancer (RIGHT Choice). ClinicalTrials.gov identifier: NCT03839823. Updated June 26, 2023. Accessed May 15, 2024. https://clinicaltrials.gov/study/NCT03839823 **16.** Data on file. CLEE011A3201C subgroup analysis. Novartis Pharmaceuticals Corp; 2023. **17.** Yardley DA, Yap YS, Azim HA, et al. Pooled exploratory analysis of survival in patients with HR+/HER2– advanced breast cancer and visceral metastases treated with ribociclib + endocrine therapy in the MONALEESA trials. Poster presented at: ESMO Congress 2022; September 9-13, 2022; Paris, France. Poster 205P.

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KISQALI has demonstrated a benefit in 1L patients with HR+/HER2- mBC, including those with aggressive disease

- Doubled mPFS vs combination chemotherapy in 1L patients with HR+/HER2- mBC who have aggressive disease
- Over 5 years mOS in 1L patients with visceral disease across 3 phase III MONALEESA trials

Isn't it time to start your next 1L patient on KISQALI?

RIGHT Choice: Efficacy results are from a subgroup analysis of patients with aggressive disease who did not have visceral crisis. In this subgroup, median PFS was 24.0 months with KISQALI + AI + goserelin (95% CI: 21.1-NE) vs 12.8 months with combination chemotherapy (95% CI: 8.5-17.5); HR=0.42 (95% CI: 0.25-0.70). Due to the nature of the study, results should be interpreted with caution. These results are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.[12,16]

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MONALEESA-3: At a median follow-up of 71 months (exploratory analysis), in a 1L subgroup analysis, median OS was 67.6 months (95% CI: 59.6-NR) with KISQALI + fulvestrant vs 51.8 months with placebo + fulvestrant (95% CI: 40.4-61.2); HR=0.673 (95% CI: 0.504-0.899). At a median follow-up of 39 months, statistical significance was established for overall survival in the ITT population; HR=0.724 (95% CI: 0.568-0.924); *P*=0.00455. PFS was the primary end point. Results from the 71-month analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error.[2,5-7]

MONALEESA-7: At a median follow-up of 54 months (exploratory analysis), median OS was 58.7 months with KISQALI + NSAI + goserelin (95% CI: 48.5-NR) vs 47.7 months with placebo + NSAI + goserelin (95% CI: 41.2-55.4); HR=0.798 (95% CI: 0.615-1.035). At a median follow-up of 35 months, statistical significance was established for overall survival in the ITT population; HR=0.71 (95% CI: 0.54-0.95); *P*=0.00973. PFS was the primary end point. Results from the 54-month analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error.[8-11]

IMPORTANT SAFETY INFORMATION

Warnings and precautions with KISQALI include interstitial lung disease/pneumonitis, severe cutaneous adverse reactions, QT interval prolongation, increased QT prolongation with concomitant use of tamoxifen, hepatobiliary toxicity, neutropenia, and embryo-fetal toxicity.

Most common (incidence ≥20%) adverse reactions include infections, nausea, fatigue, diarrhea, vomiting, headache, constipation, alopecia, cough, rash, and back pain.

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