# Confident care: effective management of adverse reactions with dose modifications



MONALEESA-2, a phase III study of KISQALI + AI vs placebo + AI in 1L postmenopausal patients: At a median follow-up of 80 months, median OS was 66.0 months (95% CI: 57.6-75.7) for patients with  $\geq 1$  dose reduction vs 60.6 months (95% CI: 42.5-79.2) for patients without dose reduction; 62.6% of patients (209/334) had  $\geq 1$  dose reduction.<sup>1-5</sup>

Dose modification of KISQALI is recommended based on individual safety and tolerability.<sup>1</sup>

### 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.

### Please see safety tables on page 7 for additional information.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



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### The majority of adverse reactions with KISQALI were transient, manageable, and reversible

### • The survival benefits observed with KISQALI were maintained in patients requiring dose reductions

### • KISQALI is the only CDK4/6 inhibitor that offers one tablet strength for straightforward dose reductions<sup>1</sup>

### In MONALEESA-2, managing adverse reactions with dose reductions helped patients stay on therapy an average of 6.5 months longer<sup>2</sup>



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# Meet Diane: a KISQALI patient with neutropenia

### Diane is a nurse at a local hospital who enjoys traveling with her husband and 2 young children.

- 43 years old
- Premenopausal
- ECOG PS: 0

### **Clinical considerations:**

- Recently diagnosed with de novo HR+/HER2- mBC
- Treatment: KISQALI + NSAI + goserelin

### Monitoring results:

- CBC with differential on Day 14 of Cycle 1 reveals ANC of 450/mm<sup>3</sup> (grade 4 neutropenia=ANC <500/mm<sup>3</sup>)
- Afebrile with no signs/symptoms of infection

View the Treatment Guide for more detailed information about grading and management of neutropenia

### **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.

**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  $\geq 2$  was 17 days. The median time to resolution of grade  $\geq 3$  (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.

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. 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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



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#### **Course of action:**

- Dose interrupted
- Two weeks after dose interruption, CBC with differential revealed ANC of 1200/mm<sup>3</sup>
- Because neutrophil counts recovered to grade <2 (ANC >1000/mm<sup>3</sup>), KISQALI resumed at reduced dose of 400 mg daily

• History of hypertension that is well controlled with medications

For patients who experience neutropenia Median time to onset of grade ≥2: 17 days Median time to resolution of grade ≥3: 12 days



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# Meet Eve: a KISQALI patient with QT prolongation

### Eve is a retired elementary school teacher who enjoys gardening and spending time with her grandchildren.

- 62 years old
- Postmenopausal
- ECOG PS: 0

### **Clinical considerations:**

- cancer diagnosed 7 years prior
- Recently diagnosed with HR+/HER2- mBC
- Treatment: KISQALI + AI

### Monitoring results:

- Baseline QTcF: 435 ms
- Cycle 1 Day 14 QTcF: 485 ms (grade 2 QT prolongation)

### **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.

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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



• Completed adjuvant treatment for stage I HR+/HER2- breast

#### **Course of action:**

- Dose interrupted
- A follow-up ECG reported a QTcF of 450 ms, allowing the patient to restart treatment at 400 mg—as QTcF prolongation resolved to <481 ms

### **KISQALI** has been shown to prolong the QT interval, but the incidence was low

1.4% (15/1054) had a >500 ms postbaseline QTcF value 6.0% (61/1054) experienced a >60 ms increase from baseline in QTcF interval

KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.<sup>1</sup>

### View the Treatment Guide for more detailed information about management of QT prolongation



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## Adverse reactions were successfully managed with no impact on overall survival benefits for patients who required dose reductions

Diane and Eve were able to continue treatment with KISQALI because adverse reactions, such as neutropenia and QT prolongation associated with KISQALI, are manageable with straightforward dose interruptions or reductions

In fact, managing adverse reactions with dose reductions helped patients stay on therapy 6.5 months longer on average (mean exposure 27.7 vs 21.2 months)<sup>2</sup>

These are not all the possible adverse reactions that may occur. Please see the additional Important Safety Information for KISQALI throughout and full Prescribing Information.

### **IMPORTANT SAFETY INFORMATION (continued)**

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  $\geq 10$  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  $\geq$ 3 ALT/AST elevation, the median time to onset was 92 days and median time to resolution to grade  $\leq$ 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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.

**PATIENT PROFILE 2** 



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## Efficacy was not impacted by dose adjustments—so you can manage adverse reactions with confidence

### Across all 3 phase III trials with KISQALI, overall survival was maintained for patients who had $\geq 1$ dose reduction<sup>2,5-8</sup>

	mOS for patients with ≥1 dose reduction	mOS for patients without dose reduct			
<b>MONALEESA-2</b> 62.6% of patients (209/334) had $\geq 1$	66.0 MONTHS (95% CI: 57.6-75.7)	<b>60.6 MONTHS</b> (95% CI: 42.5-79.2)			
dose reduction	HR=0.87 (95% CI: 0.65-1.18)				
<b>MONALEESA-7</b> 40.7% of patients (101/248) had $\geq$ 1	<b>NOT REACHED</b> (95% CI: NR-NR)	<b>NOT REACHED</b> (95% CI: NR-NR)			
dose reduction	HR=0.79 (95% CI: 0.46-1.36)				
<b>MONALEESA-3</b> 40.7% of patients $(197/484)$ had $\geq 1$	<b>NOT REACHED</b> (95% CI: 43-NR)	<b>NOT REACHED</b> (95% CI: 41.1-NR)			
dose reduction	HR=0.88 (95% CI: 0.64-1.21)				

Results are based on a post hoc analysis; efficacy in the placebo comparator arms was not assessed.

### **IMPORTANT SAFETY INFORMATION (continued)**

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  $\geq 3$  at baseline have not been established.

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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



**PATIENT PROFILE 2** 



**MONALEESA-2** was a randomized, double-blind, placebo-controlled phase III study of KISQALI + 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, 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.<sup>1,3,4,9</sup>



**MONALEESA-7** was a randomized, double-blind, placebo-controlled phase III study of KISQALI + ET (NSAI or tamoxifen) + goserelin vs placebo + ET (NSAI or tamoxifen) + goserelin (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), median OS was 58.7 months with KISQALI + NSAI + goserelin (95% CI: 48.5-NR) vs 47.7 months with 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.<sup>1,10-13</sup>

**MONALEESA-3** was a randomized, double-blind, placebo-controlled phase III study of KISQALI + fulvestrant (n=484) vs placebo + fulvestrant (n=242) for the treatment of 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, 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.<sup>1,14-16</sup>



**STRAIGHTFORWARD DOSE REDUCTIONS** 

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# Effectively manage adverse reactions without complicated dose adjustments

### One tablet strength for simple dose reductions with KISQALI<sup>1</sup>

### **Recommended starting dose**





- KISQALI is given as 600 mg (3 x 200-mg tablets) orally once daily (3 weeks on, 1 week off) with either: — An AI once daily (continuously); in premenopausal patients and men, an LHRH agonist should be administered according to current clinical practice guidelines; or
- Fulvestrant 500 mg intramuscularly on Days 1, 15, and 29, and once monthly thereafter for postmenopausal patients or men. In male patients, an LHRH agonist should be administered according to current clinical practice guidelines
- Dose adjustments for adverse reactions should be made in a stepwise order by reducing the number of tablets taken
- Dose modification of KISQALI is recommended based on individual safety and tolerability
- If dose reduction below 200 mg/day is required, discontinue treatment
- KISQALI can be taken with or without food

### **IMPORTANT SAFETY INFORMATION (continued)**

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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



**PATIENT PROFILE 2** 

Straightforward dose reductions with **KISQALI** could mean less disruption for you and your patients; no need for a new prescription or any additional cost for patients mid-cycle<sup>1</sup>

**66**...the single-tablet strength allows for simple dose adjustments, and to me, that is game changing."

> Nick McAndrew, MD University of California, Los Angeles



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# KISQALI + letrozole safety profile

### **MONALEESA-2: KISQALI + letrozole in 1L postmenopausal patients**

### ADVEDGE DEACTIONS OCCURDING IN > 100/ and > 20/ uiched than di acedoi

ADVERSE REACTIONS OCCURRING IN $\geq$ 10% AND $\geq$ 2% HIGHER THAN PLACEBO <sup>1</sup>				LABORATORY ABNORMALITIES OCCURRING IN ≥10% OF PATIENTS <sup>1</sup>							
	<b>KISQALI + LETROZOLE</b> n=334		PLACEBO + LETROZOLE n=330			<b>KISQALI + LETROZOLE</b> n=334		<b>PLACEBO + LETROZOLE</b> n=330			
	Grade 3 or 4	All grades	Grade 3 or 4	All grades		Grade 3 or 4	All grades	Grade 3 or 4	All grades		
Vomiting	3.6%	29%	0.9%	16%	HEMATOLOGY						
Decreased appetite	1.5%	19%	0.3%	15%	Neutrophil count decreased	60%	93%	1.2%	24%		
Back pain	2.1%	20%	0.3%	18%	Leukocyte count decreased	34%	93%	1.5%	29%		
Nausea	2.4%	<b>52%</b>	0.6%	29%	Lymphocyte count decreased	14%	51%	3.9%	22%		
Fatigue	2.4%	37%	0.9%	30%	Hemoglobin decreased	1.8%	57%	1.2%	26%		
Urinary tract infection	0.6%	11%	0%	8%	Platelet count decreased	0.9%	29%	0.3%	6%		
Headache	0.3%	22%	0.3%	19%	CHEMISTRY						
Insomnia	0.3%	12%	0%	9%	ALT increased	10%	46%	1.2%	36%		
Dyspnea	1.2%	12%	0.6%	9%	AST increased	7%	44%	1.5%	32%		
Diarrhea	1.2%	35%	0.9%	22%	Phosphorus decreased	5%	13%	0.6%	4%		
Constipation	1.2%	25%	0%	19%	Potassium decreased	1.2%	11%	1.2%	7%		
Stomatitis	0.3%	12%	0%	7%		1.2 /0		1.2 /0	1 /0		
Abdominal pain	1.2%	11%	0%	8%	Creatinine increased	0.6%	20%	0%	6%		
Rash	0.6%	17%	0%	8%	<ul> <li>The most common (≥20% on the KISQALI arm and ≥2% higher than placebo) adverse reactions, including laboratory abnormalities, were neutrophils decreased, leukocytes decreased, hemoglobin decreased, nausea, lymphocytes decreased, alanine aminotransferase increased, aspartate aminotransferase increased, fatigue, diarrhea, alopecia, vomiting, platelets decreased, constipation, headache, and back pain</li> </ul>						
Pruritus	0.6%	14%	0%	6%							
Pyrexia	0.3%	13%	0%	6%							
Alopecia	0%	33%	0%	16%							
Edema peripheral	0%	12%	0%	10%							

• Abnormal liver function tests included ALT increased, AST increased, and blood bilirubin increased

- Dose reductions due to ARs occurred in 45% of patients receiving KISQALI plus letrozole
- Permanent discontinuations: 7% with KISQALI + letrozole
- Patients may require dose interruption, reduction, or discontinuation for ARs. Monitoring should include: pulmonary symptoms, ECGs, serum electrolytes, LFTs, and CBCs. See Warnings and Precautions for risk of ILD/pneumonitis, SCARs, QT prolongation, hepatobiliary toxicity, neutropenia, and embryo-fetal toxicity

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**PATIENT PROFILE 2** 

• The most common grade 3/4 ARs (reported at a frequency  $\geq$ 5%): neutropenia, leukopenia, abnormal liver function tests, and lymphopenia



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## References

1L=first line; AI=aromatase inhibitor; ALT=alanine aminotransferase; ANC=absolute neutrophil count; AR=adverse reaction; AST=aspartate aminotransferase; CBC=complete blood count; CDK=cyclin-dependent kinase; ECG=electrocardiogram; ECOG PS=Eastern Cooperative Oncology Group performance status; ET=endocrine therapy; HR=hazard ratio; ILD=interstitial lung disease; ITT=intent to treat; LFT=liver function test; LHRH=luteinizing hormonereleasing hormone; mBC=metastatic breast cancer; mOS=median overall survival; NR=not reached; NSAI=nonsteroidal aromatase inhibitor; OS=overall survival; PFS=progression-free survival; QTcF=QT interval corrected by Fridericia's formula; SCAR=severe cutaneous adverse reaction.

References: 1. Kisqali. Prescribing information. Novartis Pharmaceuticals Corp. 2. Data on file. CLEE011A2301 additional analysis. Novartis Pharmaceuticals Corp; 2021. 3. 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 4. 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 5. Data on file. ML2 OS by dose reduction. Novartis Pharmaceuticals Corp; 2021. 6. Data on file. CLEE011E2301 additional analysis. Novartis Pharmaceuticals Corp; 2020. 7. Data on file. OS by dose reduction poster. Novartis Pharmaceuticals Corp; 2020. 8. Data on file. CLEE011F2301 additional analysis. Novartis Pharmaceuticals Corp; 2020. 9. Data on file. CLEE011A2301. Novartis Pharmaceuticals Corp; 2021. 10. 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 11. 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 12. Data on file. CLEE011E2301. Novartis Pharmaceuticals Corp; 2020. 13. 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 14. 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 15. Data on file. CLEE011F2301 ad hoc OS analysis. Novartis Pharmaceuticals Corp; 2022. 16. 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

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.





**STRAIGHTFORWARD DOSE REDUCTIONS** 

**SAFETY** 

### **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.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for KISQALI.



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**PATIENT PROFILE 1** 

#### **PATIENT PROFILE 2**

MANAGEABLE ADVERSE REACTIONS

66 If I...have to dose reduce because of a side effect, it's relatively easy with KISQALI because of the single-tablet strength. And ultimately, this can make it easier for my patients to stay on therapy."

> Nick McAndrew, MD University of California, Los Angeles



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Watch Dr McAndrew share his perspective

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