Adding KISQALI, CBC/LFT, and ECG to an Appropriate Treatment Plan and Creating a BPA for Appropriate Treatment Monitoring

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Maintaining up-to-date protocols in EHRs is an integral part of providing comprehensive, consistent care. To better support your health care institution, Novartis has developed this Epic EHR Guide that can be used by your EHR support or information technology departments to develop, configure, and modify EHR components relevant to treatment with KISQALI.

Introduction

This guide provides an overview of how to add KISQALI, CBC/LFT and ECG to an appropriate treatment plan and create a BPA for appropriate treatment monitoring within the Epic EHR. KISQALI monitoring and dosing information is also included for reference. The navigation tabs at the top of each page can be used to easily navigate between information.

BPA=Best Practice Alert; CBC=complete blood count; LFT=liver function test; ECG=electrocardiogram; EHR=Electronic Health Record.

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

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for KISQALI.

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Upfront ECG Monitoring

ECG and QTcF Prolongation Overview

- **ECG** measures electrical impulses as 5 waves using the letters P, Q, R, S, and T.[1]
- **QT interval** is the space between the start of the Q wave and end of the T wave, characterizing the electrical depolarization and repolarization of the heart's ventricles.[1,2]
- **QTc** is a QT interval measurement corrected to compare QT intervals at different heart rates.[2]
- **QTcF** is a QT interval corrected using the Fridericia formula.[3]
- **Prolongation of the QTc interval** is a risk factor of developing torsades de pointes or other clinically significant arrhythmias.[4]
- **Risk factors for QT interval prolongation** include medications with risk of lengthening the QT interval, 4 electrolyte imbalances (hypokalemia, hypomagnesemia, hypophosphatemia, and hypocalcemia), age, sex, bradycardia, and family/personal medical history.[4-6]

KISQALI QTcF Prolongation Incidence[3]

Low incidence of QT prolongation across all KISQALI clinical trials, and most cases were moderate in nature

In a pooled analysis across 3 phase III trials of 1054 premenopausal and postmenopausal patients treated with KISQALI + an AI or fulvestrant:

1% had a >500 ms post baseline QTcF value

6% experienced a >60 ms increase from baseline in QTcF interval

- There were no reported cases of torsades de pointes

ECG changes were reversible with dose interruption and the majority occurred within the first 4 weeks of treatment.

AI=aromatase inhibitor.

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.

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Upfront ECG Monitoring (continued)[3]

ECG Monitoring		
Baseline		✓
Cycle 1	Day 14	✓
Cycle 2	Day 1	✓ (final scheduled)

- KISQALI should only be initiated in patients with QTcF <450 ms. In case of QTcF prolongation during therapy, more frequent monitoring is recommended
- Any additional monitoring should be performed as clinically indicated
- Monitoring requirements based on a 28-day treatment cycle

Only 3 ECGs are required—and all are completed within the first 30 days of treatment.

IMPORTANT SAFETY INFORMATION (continued)

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.

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.

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.

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Routine Laboratory Monitoring[3]

		CBC/LFT	Electrolytes
Baseline		✓	✓
Cycle 1	Day 14	✓	
Cycle 2	Day 1	✓	✓
	Day 14	✓	
Cycle 3-6	Day 1	✓	✓

- For LFTs, if grade ≥2 abnormalities are noted, more frequent monitoring is recommended
- Correct any electrolyte abnormalities prior to treatment
- Additional monitoring may be required as clinically indicated
- Monitoring requirements based on a 28-day treatment cycle

The majority of scheduled monitoring occurs within the first 2 cycles of therapy and there is no scheduled monitoring beyond Cycle 6.

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 ≥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.

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Monitoring Summary[3]

		Upfront ECG Monitoring	Routine Laboratory Monitoring	
		ECG Monitoring	CBC/LFT	Electrolytes
Baseline		✓	✓	✓
Cycle 1	Day 14	✓	✓	
Cycle 2	Day 1	✓	✓	✓
	Day 14		✓	
Cycle 3-6	Day 1		✓	✓

LAB The majority of scheduled monitoring occurs **within the first 2 cycles of therapy** and there is **no scheduled monitoring beyond Cycle 6**.

ECG **Only 3 ECGs are required**—and all are completed within the **first 30 days of treatment**.

IMPORTANT SAFETY INFORMATION (continued)

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.

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Dosing

KISQALI—the only CDK4/6 inhibitor that offers one tablet strength for simple dose reductions

Recommended starting dose	1st reduction	2nd reduction
3  tablets (600 mg)	2  tablets (400 mg)	1  tablet (200 mg)

- 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

Simple dose reductions with no need for a new prescription or additional cost to patient mid-cycle

LHRH=luteinizing hormone-releasing hormone.

IMPORTANT SAFETY INFORMATION (continued)

Hepatobiliary toxicity (continued). 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.

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.

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EHR Build Guide: Adding KISQALI, CBC/LFT, and ECG to an Appropriate Treatment Plan

- Based on clinician's need, the analyst will build out the PRL (protocol) and include all necessary pretreatment cycles and regimen cycles
- Work in collaboration with Willow/Pharmacy for eRx medication deliverables
  - Add into to the appropriate cycles
  - Standard meds should be built ahead to streamline PRL build process (eg, KVO/Flushes order group and Pre-Meds order group with med options such as Dexamethasone/DECADRON®)

Pretreatment Cycle

Step 1: Appointment Request Procedure

- This is an appointment request to go over the fundamentals of the protocol study and what the patient can expect/learn about chemotherapy before moving forward

Step 2: OP Pharmacotherapy Referral

- Order Group housing the Ambulatory referral to Pharmacotherapy Clinic (Internal Referral for organization to keep track of encounter and scheduling)

Step 3: Oral Chemo Ribociclib aka KISQALI

- Oral chemo regimen may start in the pretreatment cycle here with a take-home prescription oral chemo with instructions

Step 4: Take Home Low/Moderate Emetic Risk (No Dex)

- This Order Grouper is a standard grouper built out with Low/Moderate Emetic in this case COMPAZINE®
- In early stages of Build/Implementation, the analyst and shareholders should develop a plan for standardizing Low, Medium, and High Emetic Risk Order Groupers with the appropriate meds/med options (can be configured to include multiple and single select options)

XANDER TEST STUDY [1550] - Protocol Builder

XANDER TEST STUDY

Pre-Treatment Cycle - Perform: 1 time. Length: 1 day.

Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.

ONCBCN OP APPOINTMENT REQUEST (CHEMO TEACH)

Chemo Teaching Appointment
Appointment Request, No date restriction

OP PHARMACOTHERAPY REFERRAL - Selection mode: Single-Select. Selection requirement: None

Ambulatory referral to Pharmacotherapy Clinic
Appointment Request, Internal Referral
Selection condition: Used within a rule based order group ordering based on encounter location

ORAL CHEMO RIBOCICLIB 600 MG Q21 R 11

ribociclib 600 mg/day (200 mg x 3) Tab
Oral Chemotherapy, Every morning for 21 days, then 7 days off to complete a 28 day cycle
600 mg, Oral, Every morning, starting S, Disp-63 tablet, R-11, Normal

LH TAKE HOME LOW/MODERATE EMETIC RISK (NO DEX)

prochlorperazine (COMPAZINE) 10 MG tablet
Take-Home Medications, 10 mg, Oral, Every 6 hours PRN, starting S, Disp-30 tablet, R-3, Normal

LOPERAMIDE 4MG MAX 16MG D-30 R-1

loperamide (IMODIUM) 2 mg capsule
Take-Home Medications, Take 2 capsules (4 mg) by mouth at the onset of diarrhea, then 1 capsule (2 mg) by mouth with every subsequent episode of diarrhea for a maximum of 16 mg/day. Stop use 12 hours after diarrhea resolves. Disp-30 capsule, R-1, Normal

IMPORTANT SAFETY INFORMATION (continued)

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%.

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EHR Build Guide: Adding KISQALI, CBC/LFT, and ECG to an Appropriate Treatment Plan (continued)

Cycle 1

Step 1: ONCBCN OP APPT REQUEST

- Standard OSQ with Outpatient Oncology Beacon appointment procedure for in-clinic infusion

Step 2: ONCBCN OP APPT REQUEST (PHARMACIST FOLLOW-UP TELEVISIT)

- Standard Outpatient Appt request to schedule a follow up with Pharmacist via Tele-Visit (Zoom)
- Since KISQALI is an Oral Chemo prescription take-home medication (outpatient prescription) the pharmacist will set up the Tele-Visit to check in with patient

Step 3: ONCBCN OP LABS (CBC W ANC/OMP)

- Standard OSQ grouper with labs attached

Step 4: ECG 12 Lead Procedure

- Add in basic echocardiogram procedure order here after the OP LABS standard Order Grouper (OSQ) to show flexibility analyst has to add in specific orders on a Cycle and Day basis for clinicians

Step 5: Add Physician Communication With Further Study Instructions and ECG Use

- Consider putting Physician/Nursing/Pharmacist Communications within the protocol build so that the end-user is informed before signing and releasing days orders

Step 6: PROVIDER COMMUNICATION RIBOCICLIB

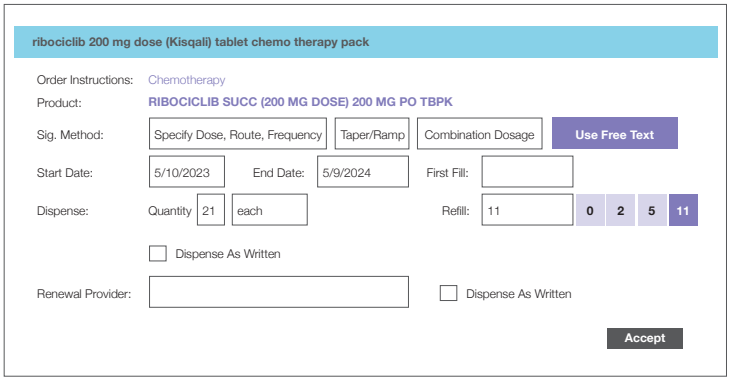
- Another OSQ Order Grouper that is explicitly labeled Physician/Provider Communication
- Physician communication provides in-depth instructions for dispensation, documentation, and baseline levels for patient observation

Pre-Treatment Cycle - Perform: 1 time. Length: 28 days.
Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
ONCBCN OP APPOINTMENT REQUEST (CLINIC MD/AP & INFUSION)
Clinic Visit Appointment Request, Schedule appointment at most 0 days before or at most 0 days after Schedule for: Established Patient With provider type: MD or Advanced Practitioner Infusion Room Appointment Appointment Request, Schedule appointment at most 0 days before or at most 0 days after
ONCBCN OP APPOINTMENT REQUEST (PHARMACIST FOLLOW UP TELEVISIT) S+7 (for testing)
Pharmacist Visit Appointment Request, Schedule appointment at most 0 days before or at most 0 days after
ONCBCN OP LABS (CBC W ANC/OMP)
ECG 12 lead Pre-Procedure, Expected: S, Expires: S+366 Physician communication Additional monitoring may be required as clinically indicated (select appropriate Order, Order Set, or Smart Set as needed). KISQALI should be initiated in patients with QTcF <450ms. In case of QTcF prolongation during therapy, more frequent monitoring is recommended.
FNR LOW PROVIDER COMMUNICATION
OP TREATMENT CONDITIONS (ANC < 1,000 / T. BILI > 2X ULN / CRCL < 30ML/MIN / AST/ALT>3XULN /QTC>480)
ribociclib (KISQALI) 600 mg/day (200 mg x 3) Tab Oral Chemotherapy, Oral, starting S
Day 15 - Perform 1 time on day 15 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
ONCBCN OP APPOINTMENT REQUEST (CLINIC MD/AP & INFUSION)
ONCBCN OP LABS (CBC W ANC/OMP)
PROVIDER COMMUNICATION RIBOCICLIB C1 D15 / C2 D1
FNR LOW PROVIDER COMMUNICATION
OP TREATMENT CONDITIONS (ANC < 1,000 / T. BILI > 2X ULN / CRCL < 30ML/MIN / AST/ALT>3XULN / QTC>480)
FULVESTRANT 500 MG IM ONCE
HYPERSENSITIVITY REACTION STANDING ORDERS
Cycle 2 - Perform: 1 time. Length: 28 days.
Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
Day 15 - Perform 1 time on day 15 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.

EHR Build Guide: Creating a BPA for Appropriate Treatment Monitoring

BPA Setup for KISQALI Treatment Monitoring

- The following information provides an overview for how a cancer center that wants to implement a BPA for their patients taking KISQALI would do so. The example used in this overview highlights how one would create a BPA for patients prescribed KISQALI but do not have appropriate baseline testing placed.
- Minimum Required Version of Epic: This guide assumes that the organization is using the Epic 2017 version or later
- Build Complexity: Low (from 1 day to 1 week)



Base Criteria—Build Process Overview

Step 1. Create a BPA criteria record.

Step 2. Create a BPA base record.

Base Criteria—Detailed Build Instructions

In Hyperspace, follow the path:

Step 1. Epic button

Step 2. Tools

Step 3. Management Console

Step 4. Decision Support

Step 5. Best Practice Advisory

IMPORTANT SAFETY INFORMATION (continued)

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.

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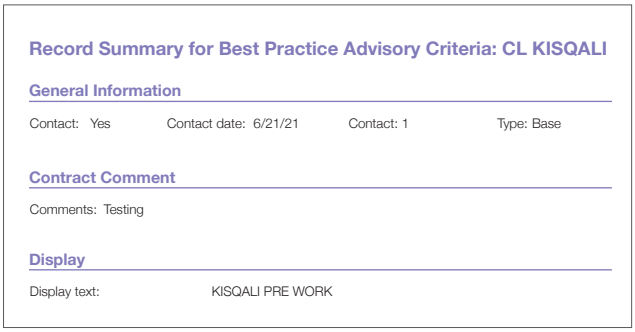
EHR Build Guide: Creating a BPA for Appropriate Treatment Monitoring (continued)

Base Criteria—Detailed Build Instructions (continued)

Step 1: Create a BPA criteria record

Create a BPA record for "PRE-TESTING for KISQALI Patients" (according to the organization's naming convention) of record type Criteria with the following settings:

- On the Contact Comment and Display pages, enter any additional information explaining the purpose of the criteria as well as the Display text you would like to see on your BPA
- On the Contact Comment page, click the Released checkbox to indicate that the BPA Criteria record is available for use


Record Summary for Best Practice Advisory Criteria: CL KISQALI

General Information

Contact: Yes Contact date: 6/21/21 Contact: 1 Type: Base

Contract Comment

Comments: Testing

Display

Display text: KISQALI PRE WORK

Hypothetical example of BPA Criteria Record

Step 2: Create a BPA base record

The BPA base record contains the logic for when to display the alert, the display text in the alert for the clinician, where in the chart the alert appears, and appropriate follow-up actions. The triggering action for the BPA **is an order for KISQALI**.

- Create a BPA record for "TESTING REQUIREMENTS FOR KISQALI Patients" (according to your organization's naming convention) of record type Base with the following settings:
  - On the Contact Comment and Display pages, enter the following:
    - > Display Text: "Pre-Workup and ongoing monitoring is required."
    - > Display to user: YES to display in workflows such as the storyboard, general BPA sections, and via chart review
    - > Include links to guidelines if requested by cancer center clinicians
  - On the Restrictions page, enter any encounter filtering restrictions under the **INCLUDE ENCOUNTER RESTRICTION**

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.

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Notes

- The Customers (ie, physician, medical group, integrated delivery network [IDN]) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each individual EHR system vary. Novartis shall not be responsible for revising the implementation instructions it provides to any Customer in the event that Customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Novartis
- While Novartis tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Novartis shall have no liability thereto
- The instructions have not been designed to meet and are not tools and/or solutions for meeting Meaningful Use, Advancing Care Information, and/or any other quality/accreditation requirement
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IMPORTANT SAFETY INFORMATION (continued)

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, creatinin increased, platelets decreased, and glucose serum decreased.**

References: 1. Mayo Clinic. Long QT syndrome diagnosis & treatment. https://www.mayoclinic.org/diseases-conditions/long-qt-syndrome/diagnosis-treatment/drc-20352524. Accessed July 27, 2023. **2.** Vandenberk B, et al. *J Am Heart Assoc.* 2016;5(6):e003264. **3.** Kisqali. Prescribing Information. Novartis Pharmaceuticals Corp. **4.** Mayo Clinic. Long QT syndrome symptoms & causes. https://www.mayoclinic.org/diseases-conditions/longqt-syndrome/symptoms-causes/syc-20352518. Accessed July 27, 2023. **5.** Al-Khatib SM, et al. JAMA.2003;289(16):2120-2127. **6.** Vered I, et al. *J Bone Miner Res.*1990;5(5):469-474.

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