



THE MONALEESA CLINICAL TRIAL PROGRAM

MONALEESA-3 and -7 are randomized Phase III trials dedicated to evaluating a CDK4/6 inhibitor in women with HR+/HER2- metastatic breast cancer who are postmenopausal and premenopausal, respectively. The MONALEESA clinical trial program established Kisqali as the CDK4/6 inhibitor demonstrating the longest median overall survival ever reported across two Phase III metastatic breast cancer trials with distinct patient populations.^{1,2,3,4}

The Unmet Need in Metastatic Breast Cancer:

Breast cancer recently became the most commonly diagnosed cancer in the world and an estimated

361,826 ARE DIAGNOSED WITH METASTATIC BREAST CANCER EACH YEAR AROUND THE GLOBE.^{5,6,7}

Kisqali offers the chance for more life to those affected by HR+/HER2- metastatic breast cancer, which is the most common type of breast cancer.

In **premenopausal women, HR+/HER2- metastatic breast cancer** is biologically distinct and more aggressive, taking the lives of more

WOMEN 20-59 YEARS OLD THAN ANY OTHER TYPE OF CANCER.^{8,9}

Overall survival, a clinical trial endpoint, is the total length of time after someone begins treatment that he or she continues to live. In a clinical trial, it is a direct way to see if a treatment helped people live longer compared to another treatment. In other terms, it's about **adding more days to a person's life**.

	MONALEESA-7	MONALEESA-3
ABOUT THE TRIAL	<ul style="list-style-type: none"> • Kisqali + endocrine therapy vs endocrine therapy alone as first line treatment for premenopausal women with HR+/HER2- advanced breast cancer • 672 women enrolled² 	<ul style="list-style-type: none"> • Kisqali + fulvestrant vs fulvestrant alone as first- or second-line treatment for postmenopausal women with HR+/HER2- advanced breast cancer • 726 women enrolled⁴
OVERALL SURVIVAL +	<ul style="list-style-type: none"> • Kisqali + endocrine therapy demonstrated statistically significant overall survival results compared to endocrine therapy alone.² • Overall survival at 42 months:² <ul style="list-style-type: none"> » 70% for women who received Kisqali + endocrine therapy vs 46% for women who received endocrine therapy alone (HR=0.71; p=0.00973) 	<ul style="list-style-type: none"> • Kisqali + fulvestrant demonstrated statistically significant overall survival results compared to fulvestrant alone.⁴ • Overall survival at 42 months:⁴ <ul style="list-style-type: none"> » 58% for women who received Kisqali combination treatment vs 46% for women who received fulvestrant alone (HR= 0.72; p=0.00455)
MEDIAN OVERALL SURVIVAL 📊	<ul style="list-style-type: none"> • Kisqali + endocrine therapy had a median overall survival of 58.7 months, compared to endocrine therapy alone.¹ • Median OS:¹ <ul style="list-style-type: none"> » 58.7 months for women who received Kisqali + endocrine therapy vs 48 months for women who received endocrine therapy alone (HR=0.76 [95% CI, 0.61-0.96]) 	<ul style="list-style-type: none"> • Kisqali + fulvestrant had a median overall survival of 53.7 months, compared to fulvestrant alone.³ • Median OS:³ <ul style="list-style-type: none"> » 53.7 months for women who received Kisqali + fulvestrant vs 41.5 months for women who received fulvestrant alone (HR=0.73 [95% CI, 0.59-1.04])
SAFETY 🛡️	<ul style="list-style-type: none"> • Kisqali is not indicated for use with tamoxifen. • Most common grade 3/4 AEs for Kisqali combination therapy vs endocrine therapy alone:² <ul style="list-style-type: none"> » Neutropenia (63.5% vs 4.5%) » Hepatobiliary toxicity (11% vs 6.8%) • Discontinuation rate due to AEs: 3.3% (Kisqali combination therapy) vs 3.9% (endocrine therapy alone)² 	<ul style="list-style-type: none"> • Most common grade 3/4 AEs for Kisqali + fulvestrant vs fulvestrant alone:⁴ <ul style="list-style-type: none"> » Neutropenia (57.1% vs 0.8%) » Leukopenia (15.5% vs 0%) • Discontinuation rate due to AEs: 8.9% (Kisqali + fulvestrant) vs 3.7% (fulvestrant alone)⁴

RESEARCH IS ONGOING, AND OVERALL SURVIVAL ANALYSIS OF **KISQALI** AS A FIRST-LINE TREATMENT FOR POSTMENOPAUSAL PATIENTS IN THE MONALEESA-2 CLINICAL TRIAL IS UNDERWAY.





IMPORTANT SAFETY INFORMATION

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What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

Lung problems. KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your health care provider right away if you have any new or worsening symptoms, including:

- trouble breathing or shortness of breath
- cough with or without mucus
- chest pain

Severe skin reactions. Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse; reddened skin; flu-like symptoms; skin pain/burning; blistering of the lips, eyes, or mouth; or blisters on the skin or skin peeling, with or without fever.

Heart rhythm problems (QT prolongation). KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your health care provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.

Liver problems (hepatobiliary toxicity). KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark or brown (tea-colored) urine
- loss of appetite
- feeling very tired
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking KISQALI and may result in infections that may be severe. Your health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your health care provider may tell you to decrease your dose, temporarily stop, or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

What should I tell my health care provider before taking KISQALI?

Before you take KISQALI, tell your health care provider if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)

- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby
 - > If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.
 - > Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
 - > Talk to your health care provider about birth control methods that may be right for you during this time.
 - > If you become pregnant or think you are pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other, causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and avoid drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

The most common side effects of KISQALI include:

- neutropenia
- nausea
- infections
- fatigue
- diarrhea
- leukopenia
- vomiting
- hair loss
- headache
- constipation
- rash
- cough

KISQALI may cause fertility problems if you are male and take KISQALI. This may affect your ability to father a child. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.





REFERENCES

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References

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