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Kisqali® (ribociclib) in HR+/HER2- Advanced or Metastatic Breast Cancer

Kisqali® (ribociclib) is approved by the US FDA in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer.

Kisqali was approved based on a first-line, Phase III trial (MONALEESA-2) that met its primary endpoint at interim analysis due to significant improvement in progression-free survival (PFS) compared to letrozole alone¹.

Kisqali was reviewed and approved under the FDA Breakthrough Therapy designation and Priority Review programs.

How It Works

Kisqali is a cyclin-dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated, can enable cancer cells to grow and divide too quickly^{1,2}.

Targeting CDK4/6 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably^{1,2}.

Demonstrated Efficacy

Breast Health

About one in eight women in the U.S. will develop invasive breast cancer during their lifetime.

No.1

Breast cancer is the most common cancer among American women, except for skin cancers.

No.2

Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer.

232,670

Estimated amount of new cases of invasive breast cancer diagnosed in women.

2.8 million

Estimated amount of breast cancer survivors in the U.S.

55+

Two of three breast cancers are found in women 55 or older.

Breast cancer survivorship has tripled over the past 60 years.

Risk Factors

- GENDER**: A woman is 200 times more likely than a man to develop breast cancer.
- AGE**: Your risk of developing breast cancer increases as you get older, and half of all breast cancers are diagnosed in women older than 60.
- GENETICS**: About 5 to 10 percent of breast cancer cases are thought to be hereditary, meaning that they result directly from gene defects inherited from a parent.
- FAMILY HISTORY**: Risk is higher among women whose close blood relatives have this disease. Less than 15 percent of women with breast cancer have a family member with this disease.
- WEIGHT**: Being overweight or obese increases breast cancer risk.
- RACE**: Overall, white women are slightly more likely to develop breast cancer than African-American women, but African-American women are more likely to die of this cancer.

Health Tips

- BREAST DENSITY**: Having dense breasts makes your chance for breast cancer four times higher.
- KNOW YOUR FAMILY HISTORY**: 5 to 10 percent of breast cancer is hereditary.
- NUTRITION**: Eat five or more servings of fruit and vegetables daily, limiting processed and red meats. Choose whole grains.
- SCREENING**: Remember to get annual mammograms and clinical breast exams beginning at 40.
- WATCH WEIGHT**: Women who gained 21 to 30 pounds since age 18 were 40 percent more likely to develop breast cancer than those who hadn't gained more than five pounds.
- PHYSICAL ACTIVITY**: Women who walk briskly for 1.25 to 2.5 hours a week had 18 percent less risk than women who are inactive.
- ALCOHOL**: Limit alcohol consumption to no more than one drink a day — any more than that increases risk by 15 times compared to someone who doesn't drink.
- SUPERFOODS**: City of Hope researchers have discovered that pomegranates, grape seed extract and blueberries all have powerful breast cancer fighting agents.

Symptoms

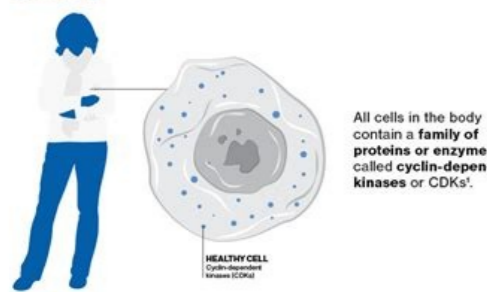
- Swelling of all or part of the breast
- Skin irritation or dimpling
- Breast or nipple pain
- Nipple retraction (turning inward)
- Redness, scaliness or thickening of nipple or breast skin
- Nipple discharge



Cyclin-Dependent Kinase (CDK) Inhibitors in Advanced or Metastatic Breast Cancer

What are cyclin-dependent kinases (CDKs)?

CDKs are a family of proteins or enzymes found in all cells in the body



The Importance of CDKs

CDKs are important in controlling the normal life cycle of cells as they are used to make new cells

Genetic changes to CDK4 and CDK6 have been found in many cancer cells, including breast cancer.

Effects of Genetic Changes in Cancer Cells

Cancer consists of cells that grow, divide and spread too quickly without control. In most cancer cells, the CDK4/6 enzymes are over-activated by abnormal genetic changes. When CDK4/6 enzymes are over-activated it causes the cancer cells to divide too quickly, creating a tumor.

Therapeutic Targeting of CDK4/6

CDK4/6 Inhibitors Help to Slow the Progression of Cancer

Targeting CDK4/6 enzymes may play a role in ensuring that cancer cells do not continue to replicate uncontrolled, spreading cancer.



American cancer society facts. American cancer society recommendations for self breast exam.

The factors are also in detail related to hormone receptors, to protein HER2 and the growth rate of the cells. The process is complicated but necessary to determine the best treatment plan for your particular type of cancer. What about Ayurvedic medicine from India? The tests are a way to get to a state-of-the-art treatment center, and for some, this is the only way to access the latest treatments. The annual reports of facts and figures provides: estimated numbers of new cases of cancer and deaths in 2021 (in 2021, there will be about 1.9 million new cases of cancer diagnosed and 608.57 years of cancer deaths in the United States.) Current incidence of cancer, mortality and survival statistics About cancer symptoms, risk factors, early detection and treatment (Note: The expected number of cancer cases and deaths in 2021 should not be compared with previous years To keep track of cancer trends because they are based on models and vary from year to year for reasons other than cancer processing. The goal is to be proactive and work with the doctor to evaluate possible signs of breast cancer - But without a panic. Detecting breast cancer in the early stages before it progresses very often leading to positive results. You can also consider alternative or complementary methods And get ready to face this head and never feel like I was only on Thi S. The disease has no barriers when it comes to gender, ethnicity or race, and anyone who could potentially develop it, in particular if they have some risk factors, like the Previous contraceptive use or oral hormone, genetic factors and family history. This is equivalent to an average risk of about 13%. This phase is often indicated as metastatic breast cancer and is more difficult to treat due to On other organs. Tumor cells can be destroyed with therapy, although there is no guarantee that doctors doctors will work so Use the term "healing intention" rather than cure. For men, the risk of developing breast cancer is much lower than women, about 100 times lower for white men, in fact. Most tables and figures required the most requested tables and figures from Facts & Figures 2021 have been assembled in an electronic format (PDF) to simplify use. After treatment, it takes many years before a doctor confirms that cancer was treated. The stage in which it has been discovered, whether you are pre or post menopause, along with other factors require the best way to act for you, but take a look at some of the treatments there outside. The body of cancer and the prevention of the return are the reasons for surgery. The standardized incidence for ages and mortality rates should be used to measure cancer trends.) Á, This year's special section focuses on the impact of Covid-19 pandemic on people living with cancer, ie. Cancer surveillance capacity and the American health care system. On average, about one of 833 men develop breast cancer. The symptoms of early breast cancer is obviously quite common, particularly in women, to cause concern, but an early detection can overturn the stairs in favor of a positive result. Mastectomy may need to remove the entire breast or surgery to remove the tumor and fabric surrounding it. Women could have all the symptoms of breast cancer or just a few, so it is important to be diligent for all potential signs. Chemiots can reduce tumors and prevent the spread of cancer, which makes patients feel better and live a longer life. Women with diagnosis of breast cancer that have not spread outside the breast have a survival relating to five years of about 99%. Being brigade and watching the first signs of breast cancer is one of the most effective steps in successful treatment. Once the cancer spreads to other parts of the chest or to the Al Nodes, the five-year survival rate drops to 86%, which is still a very positive prognosis. The symptoms of IV stage cancer include visible swelling in the breast and in the Asclaire; dry and shaky skin; red and rippled leather; secretion from the nipple; Breast pain; fatigue; insomnia; loss of appetite; weight loss; Payment of breath and other symptoms related to the specific organs involved. In the simpler terms - the complete staging system has numerous understans - the stage 0 involves potentially abnormal cells, but a tumor has been located. However, most women who develop breast cancer do not have a family history. If surgery is the best way to act, the size of the tumor and the spread of diffusion will determine the type of surgery. This aims to harmonize the spirit, body and mind through food, meditation and massage. The ACS regions are encouraged to share this information with staff and volunteers and to use them with state and local officials, journalists and other public health groups and defense in the local communities. Stadium III is the first stage considered an advanced breast cancer, with cancer that has probably widespread in other parts of the chest and lymph nodes. The risk increases about three times more likely if they have more than one relative in this narrow family group with breast cancer. In the IV phase, cancer has spread to other bodies and body parts beyond the breast. The phases of breast cancer if you are diagnosed with mammary carcinoma, doctors and pathologists will examine the results of biopsy and imaging to determine the stage - also known as progression - of the disease. There are several treatments that doctors recommend. These treatments work for some people, but they are not probably present in the list of Your oncologist. In conclusion, use every stage, this is your body and you have the choice. This section aims to inform any person (who (who Political managers, researchers, clinicians, supporters of cancer control, patients and / or caregivers) with interest in the long -term consequences of pandemic on cancer health problems. If cancer has spread to the lymph nodes under the arm, this could cause swelling in the axle. Men need to remain vigilant to make sure that the first signs of male breast cancer do not fail. If the tumor has ávelop "receptors" for protein, estrogen and progesterone, so the surgeon must take it into consideration. The symptoms of breast cancer in men for men, breast cancer is very Less common, and it could be easier to neglect the symptoms. Although the percentage of cases in men is much lower than that of women, male breast cancer represents a portion of new cases every year. ats Cancer Facts & Figures 2021 is " an educational partner for the statistics of cancer 2021, a scientific document published in the American Cancer Society Journal, CA: a cancer newspaper for doctors. Many of the symptoms could also be signs of other less serious conditions. Black men, D 'Other part, they are only about 70 times less likely to develop it of black women. Some women can see pain or a red eruption and irritated in a certain area that does not go away, and lumps can be felt or they too re visible in the breast or in the Ascocca area. If this interests you, start asking your doctor if the hospital or clinic manages clinical studies and benefits from them. Online treatments. Internal treatments can include traditional Chinese medicine such as acupuncture, Tai Chi and massage. Only about 15% of women have other family members who have previously been diagnosed with the disease. In addition, the facts and figures regularly updated publications present trends updated in the attention of cancer and survival, as well as information on symptoms, prevention, early detection and treatment. If cancer has spread to other parts of the body, body, It becomes more difficult, and the relative rate of relative five-year survival drops to 27%. For appetizers, it is important to pay attention to the aspect of the breast, since one of the first signs of breast cancer is a change in size of the breast or form due to swelling or other factors. Breast cancer statistics and facts about eight women in the United States will develop invasive breast cancer. The veins that become more important, the dull in the breast tissue and the discharge of the nipple are also signs that should be studied. The estimated number of new cases of cancer and deaths by state and the probabilities of development life or die of cancer are also available in an interactive format from the Cancer Statistical Center. These are called to unlock internal energy lines that pass through your body. Please note that all graphic materials should credit the "American Cancer Society, Cancer facts and figures 2021.á.á.á. ~ Trends in cutting-edge cancer of mortality rates for site, males, US, 1930- 2018 (PDF) Trends in cancer adjusted by the age Death rates for site, females, US, 1930-2018 (PDF) Estimated number of new cancer cases and deaths by sex, US, 2021 (pdf) Estimated number of new cases For the tumors selected by state, US, 2021 (PDF) Estimated Number of deaths for selected tumors by state, United States, 2021 (PDF) Leading sites of new cancer cases and deaths - 2021 estimates (pdf) Probability of developing the INVASIVE CANCER During the selected age incidence for gender, US, 2015-2017 (PDF) and mortality rates for selected tumors for race and ethnicity, United States, 2013-2018 (pdf) Cancer statistics 2021 Presentation of the slide use The button to download a slide presentation of an overview D Current creatures cancer statistics in the United States. Photo of courtesy: / Twitter Breast cancer is the second most common cancer found in women Á ε.á. ~ "after skin cancer - but does not mean that men also mean at risk. These research studies carefully checked controlled Promising new procedures and treatments to be tested. Don't feel the railway in the treatment so take the á ε

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