Novartis receives FDA approval for first-of-its-kind Kisqali® Femara® Co-Pack for initial treatment of HR+/HER2- advanced or metastatic breast cancer

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- Physicians now have the option of prescribing Kisqali and Femara together in one convenient co-pack
- Co-Pack allows patients ability to obtain Kisqali and Femara with a single co-pay
- Approval comes less than two months after Kisqali received US FDA approval

East Hanover, N.J., May 8, 2017 – Novartis announced today that the US Food and Drug Administration (FDA) has approved the Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets) for the treatment of hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in postmenopausal women[1]. The Kisqali Femara Co-Pack is the first, and only currently available, combination pack with two prescription products in advanced breast cancer.

With this FDA approval, physicians in the United States now have the flexibility to prescribe Kisqali two different ways: via the new Co-Pack or as two separate prescriptions of Kisqali and any aromatase inhibitor.

“As we strive to keep the patient at the center of every decision that we make at Novartis, we are pleased that collaborating closely with the FDA has resulted in our being able to offer this unique combination pack of two prescription cancer medicines,” said Bill Hinshaw, Executive Vice President and Head, US, Novartis Oncology. “Providing physicians a convenient one package prescribing option for their patients underscores our commitment to deliver innovative treatment solutions to the metastatic breast cancer community.”

The innovative packaging of the Kisqali Femara Co-Pack allows patients the convenience of obtaining a full 28-day cycle of the two medicines in one package with one prescription and one co-pay. The Kisqali Femara Co-Pack is available at the same cost as Kisqali alone.

The Kisqali Femara Co-Pack is available in three dosage strengths: Kisqali 600 mg plus Femara 2.5 mg, Kisqali 400 mg plus Femara 2.5 mg, and Kisqali 200 mg plus Femara 2.5 mg. The Kisqali Femara Co-Pack will be available in the US later this month at both specialty and retail pharmacies, and does not change the indication for either medicine.

Kisqali was approved on March 13, 2017 in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with HR+/HER2- advanced or metastatic breast cancer[2].

Femara is an aromatase inhibitor approved for first-line treatment of postmenopausal women with HR+ or unknown advanced breast cancer[3]. Developed by Novartis, Femara has been a standard of care option for more than a decade in early and advanced breast cancer.

About Kisqali® (ribociclib)

Kisqali® (ribociclib) is a selective 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. Targeting CDK4/6 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably.

Kisqali was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

About Femara® (letrozole)

Femara® (letrozole) is a form of hormone therapy known as an aromatase inhibitor, which works by reducing the amount of estrogen produced in the bodies of postmenopausal women. Femara was first approved in 1997 for treatment of postmenopausal women with HR+ or unknown advanced breast cancer that progressed after antiestrogen therapy. In 2001, Femara was approved as first-line treatment of postmenopausal women with HR+ or unknown locally advanced or metastatic breast cancer.

Femara has been available for nearly 20 years and research by Novartis has continued during this time.

Kisqali® (ribociclib) and Femara® (letrozole) Important Safety Information

Kisqali® (ribociclib) is a prescription medicine used in combination with an aromatase inhibitor as the first hormonal-based therapy to treat women who have gone through menopause with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. The Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets) is a prescription medicine used as the first hormonal based therapy to treat women who have gone through menopause with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer. The Kisqali Femara Co-Pack contains 2 different types of medicines: Kisqali and Femara. It is not known if Kisqali or the Kisqali Femara Co-Pack is safe and effective in children. Kisqali or the Kisqali Femara Co-Pack can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Patients should tell their health care provider right away if they have a change in their heartbeat (a fast or irregular heartbeat), or if they feel dizzy or faint. Kisqali or the Kisqali Femara Co-Pack can cause serious liver problems. Patients should tell their health care provider right away if they get any of the following signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), dark or brown (tea-colored) urine, feeling very tired, loss of appetite, pain on the upper right side of the stomach area (abdomen), and bleeding or bruising more easily than normal. Low white blood cell counts are very common when taking

Kisqali or the Kisqali Femara Co-Pack and may result in infections that may be severe. Patients should tell their health care provider right away if they have signs and symptoms of low white blood cell counts or infections such as fever and chills. Before taking Kisqali or the Kisqali Femara Co-Pack, patients should tell their health care provider if they are pregnant, or plan to become pregnant as Kisqali or the Kisqali Femara Co-Pack can harm an unborn baby. Females who are able to become pregnant and who take Kisqali or the Kisqali Femara Co-Pack should use effective birth control during treatment and for at least 3 weeks after the last dose. Do not breastfeed during treatment with Kisqali or the Kisqali Femara Co-Pack and for at least 3 weeks after the last dose. Patients should tell their health care provider about all of the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements since they may interact with Kisqali. Patients should avoid pomegranate or pomegranate juice, and grapefruit or grapefruit juice while taking Kisqali or the Kisqali Femara Co-Pack. The most common side effects (incidence ≥20%) of Kisqali + letrozole are white blood cell count decreases, nausea, tiredness, diarrhea, hair thinning or hair loss, vomiting, constipation, headache, and back pain. The most common grade 3/4 side effects in the Kisqali + letrozole arm (incidence >2%) were low neutrophils, low leukocytes, abnormal liver function tests, low lymphocytes, and vomiting. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

Please see full Prescribing Information for the Kisqali Femara Co-Pack, available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/fil….

About Novartis in Advanced Breast Cancer

For more than 25 years, Novartis has been at the forefront of driving scientific advancements for breast cancer patients and improving clinical practice in collaboration with the global community. With one of the most diverse breast cancer pipelines and the largest number of breast cancer compounds in development, Novartis leads the industry in discovery of new therapies and combinations, especially in HR+ advanced breast cancer, the most common form of the disease.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “strive,” “offer,” “commitment,” “will,” “may,” “pipelines,” “in development,” or similar terms, or by express or implied discussions regarding potential additional marketing approvals for the Kisqali Femara Co-Pack, or for Kisqali or Femara individually, or regarding potential future revenues from the Kisqali Femara Co-Pack, or Kisqali or Femara individually. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the Kisqali Femara Co-Pack, or Kisqali or Femara individually will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that the Kisqali Femara Co-Pack, or Kisqali or Femara individually will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that the Kisqali Femara Co-Pack, or Kisqali or Femara individually will be commercially successful in the future. In particular, management’s expectations regarding the Kisqali Femara Co-Pack, and Kisqali and Femara individually could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the company’s ability to

obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing and reimbursement pressures; safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Located in East Hanover, NJ, Novartis Pharmaceuticals Corporation is an affiliate of Novartis which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis and @Novartis Cancer at http://twitter.com/novartiscancer.

For Novartis multimedia content, please visit www.novartis.com/news/media-library.

For questions about the site or required registration, please contact media.relations@novartis.com.

References

1. Kisqali Femara Co-Pack [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017.

2. Kisqali [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017.

3. Femara [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 1997.

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