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VIDEO: Femara® helps protect against return of breast cancer even when treatment starts several years after completing tamoxifen therapy

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- - Post-unblinding analysis of MA-17 trial data provides evidence for potential benefit of starting Femara up to seven years after finishing tamoxifen
- - Femara only member of aromatase inhibitor class with data demonstrating this potential benefit, as published in Journal of Clinical Oncology
- - Half of all breast cancer recurrences occur five or more years after diagnosis
- - Separate analysis published in Annals of Oncology affirms significant advantages of Femara when taken after standard tamoxifen therapy

EAST HANOVER, N.J., March 10 /PRNewswire-FirstCall/ -- Women may reduce the risk of their breast cancer returning by starting treatment with Femara® (letrozole tablets) anywhere from one to seven years after finishing tamoxifen therapy, according to a new analysis published today in the Journal of Clinical Oncology(1).

To view the Multimedia News Release, go to:
http://www.prnewswire.com/mnr/novartis/32189/

The exploratory analysis of post-unblinding results from the landmark MA-17 trial, led by the National Cancer Institute of Canada Clinical Trials Group, evaluated a subset of women in the original placebo group when the study was unblinded.

The analysis shows that women who started Femara several years after completing the recommended five years of tamoxifen reduced their risk of breast cancer coming back by 63% compared to those who did not start Femara(1). In addition, the risk of cancer spreading to other areas of the body was reduced by 61%. The median period before starting Femara was 31 months.

"The important message for women is that it may never be too late for many breast cancer survivors to do more to protect themselves against the ongoing risk of disease recurrence," said Paul Goss, M.D., PhD., of the Massachusetts General Hospital in Boston and the lead investigator of MA-17. "These data reinforce the need for women diagnosed with breast cancer to go back to their doctors and continue to discuss ways to reduce their risk of recurrence."

More than 50% of breast cancer recurrences and deaths occur five or more years after completing tamoxifen treatment(1). Femara is the only drug in the aromatase inhibitor class with data showing its potential to reduce the risk of breast cancer returning even when started several years after initial treatment with tamoxifen.

A separate intent-to-treat analysis of unblinded results from the MA-17 trial, published today in the Annals of Oncology, supports the significant benefit of initiating Femara within three months of completing five years of tamoxifen(2). If women do not have the opportunity to begin Femara treatment within three months of completing tamoxifen, the exploratory analysis published in the Journal of Clinical Oncology indicates they may still benefit from starting Femara up to several years later.

MA-17 was an international, double-blinded, randomized, multi-center Phase III trial to evaluate the effectiveness of Femara versus placebo in breast cancer survivors who had completed five years of tamoxifen treatment. It was led by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario with funding from the Canadian Cancer Society and support from Novartis.

The trial was unblinded in 2003 after the first planned interim analysis showed a marked benefit for Femara in reducing the risk of breast cancer recurrence(2). At that time, women in the placebo arm were offered the chance to start treatment with Femara or to continue without additional treatment.

The analysis published in the Journal of Clinical Oncology evaluated the subset of 2,383 women who were in the placebo group when the MA-17 trial was unblinded. Of these women, 1,579 chose to switch to Femara, while 804 chose not to start Femara. The safety analysis was consistent with many other Femara trials in various treatment settings, reinforcing that Femara is well tolerated.

"Novartis has the highest level of commitment to ensuring that women with breast cancer have the knowledge and therapies to reduce their risk of recurrence, whether they were diagnosed yesterday or many years ago," said Diane Young, M.D., Head of Global Medical Affairs at Novartis Oncology. "Femara offers protection against recurrence throughout several phases of breast cancer treatment in women with hormone-sensitive early breast cancer. These new data add to the body of clinical evidence for Femara."

The intent-to-treat analysis published in the Annals of Oncology evaluated the outcomes for women assigned to Femara and placebo in the original trial study arms. At a median follow-up of 64 months, Femara significantly reduced the risk of breast cancer recurrence by 32% versus placebo. Femara maintained its significant benefit over placebo, even though more than 60% of women in the placebo group started Femara when the study was unblinded.

Results from this analysis affirm the safety and efficacy of Femara as extended adjuvant therapy (i.e. following the completion of five years of tamoxifen).

About Femara

Femara® (letrozole tablets) is approved for the adjuvant (following surgery) treatment of postmenopausal women with hormone receptor-positive early stage breast cancer. The benefits of Femara in clinical trials are based on 24 months of treatment. Further follow-up will be needed to determine long- term results, safety and efficacy.

Femara is also approved for the extended adjuvant treatment of early stage breast cancer in postmenopausal women who are within three months of completion of five years of tamoxifen therapy. The benefits of Femara in clinical trial are based on 24 months of treatment. Further follow-up will be needed to determine long-term results, including side effects.

In addition, Femara is approved for the treatment of postmenopausal women with estrogen receptor-positive or estrogen receptor-unknown breast cancer that has spread to another part of the body (metastatic cancer).

Important Safety Information

You should not take Femara if you are premenopausal. Your doctor should discuss the need for adequate birth control if you have the potential to become pregnant, if you are not sure of your postmenopausal status, or if you recently became postmenopausal. Femara is only indicated in postmenopausal women. Talk to your doctor if you're allergic to Femara or any of its ingredients. You should not take Femara if you are pregnant as it may cause fetal harm. Some women reported fatigue and dizziness with Femara. Until you know how it affects you, use caution before driving or operating machinery. Some patients taking Femara had an increase

in cholesterol. Additional follow- up is needed to determine the risk of bone fracture associated with long-term use of Femara.

In the adjuvant setting, commonly reported side effects are generally mild to moderate. The most common side effects seen with Femara include hot flashes, joint pain, night sweats, weight gain, nausea, tiredness, other heart-related events and bone fractures. Other less commonly reported side effects include vaginal bleeding, blood clots, other cancers, osteoporosis, stroke, heart attack and endometrial cancer.

In the extended adjuvant setting, commonly reported side effects are generally mild to moderate. Commonly reported side effects for Femara include hot flashes, fatigue, joint pain, headache, increase in sweating, swelling due to fluid retention, increase in cholesterol, dizziness, constipation, nausea, cardiovascular ischemic events, muscle pain, osteoporosis, arthritis and bone fracture.

In the metastatic cancer setting, commonly reported side effects are generally mild to moderate and may include bone pain, hot flashes, back pain, nausea, joint pain, shortness of breath, tiredness, coughing, constipation, limb pain, chest pain and headache.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "potential", "may", "to be", or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Femara or regarding potential future revenues from Femara. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Femara will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Femara could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, gastrointestinal and respiratory areas. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines

and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.pharma.us.novartis.com/.

Additional press information available at http://novartisoncologyvpo.com/.

References
1. Goss PE, Ingle JN, Pater JL, et al. Late extended adjuvant treatment with letrozole improves outcome in women with early-stage breast cancer completing 5 years of tamoxifen. J Clin Oncol. 2008
2. Ingle JN, Tu D. Pater JL , et al. Intent-to-treat analysis of the placebo-controlled trial of letrozole for extended adjuvant therapy in early breast cancer: NCIC CTG MA.17. Annals of Oncology. 2008

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