Study Confirms An Optimal Breast Cancer Treatment Approach Vs. Tamoxifen After Surgery In Hormone Receptor-Positive Postmenopausal Early Breast Cancer

(NAPSA)—Approximately one in three women who have hormone receptor-positive (HR+) breast cancer are faced with their disease either returning or spreading to another part of their body, one of the main reasons why more than 500,000 women worldwide lose their lives to breast cancer each year. The incidence of breast cancer has been rising in recent decades, further emphasizing the importance of patients working with their physician to find a treatment approach that works best for them. However, at the same time, breast cancer research has led to many significant discoveries, and doctors are learning more every day about the most effective ways to prevent breast cancer from returning or spreading.

Important results from one such clinical trial that were recently published in The New England Journal of Medicine (NEJM) show that a drug called Femara® (letrozole tablets) can help play a critical role in minimizing the risk of HR+ early breast cancer returning and spreading in postmenopausal women following surgery to remove tumors versus tamoxifen.

Facts and Figures

- Cancer returning or spreading is the primary cause of death from breast cancer.
- An important clinical trial confirmed that a drug called Femara is an optimal long-term treatment strategy after surgery versus tamoxifen for hormone receptor-positive postmenopausal early stage breast cancer patients.

The study compared postmenopausal women with HR+ early breast cancer who took Femara for five years after having breast surgery to women who took another drug, tamoxifen, for the same amount of time. In addition, the study evaluated women who took a sequence of either Femara and/or tamoxifen.

However, the study confirmed that neither of the sequenced approaches were significantly better than treatment with Femara alone in reducing the risk of breast cancer returning, also known as disease-free survival. The study also affirmed Femara as a better choice for reducing the risk of breast cancer returning in postmenopausal women with HR+ early breast cancer than tamoxifen. Not only did Femara demonstrate improvement in disease-free survival, but it also reduced the risk of the disease spreading to another part of the body, known as metastasis, as compared to tamoxifen.

"The data show the significant long-term benefit of Femara, and these results will likely have an impact on how doctors treat patients in the U.S.," said Dr. Kimberly Blackwell, a leading breast cancer researcher and associate professor of medicine at the Duke University Medical Center.

The ultimate goal in treating breast cancer patients after they have had surgery to remove their tumor is to prevent the disease from returning in the future. This clinical trial confirmed that Femara is an optimal treatment strategy after surgery compared to tamoxifen and may offer postmenopausal, HR+ early breast cancer patients the opportunity to further reduce recurrence versus tamoxifen.

These long-term results published in NEJM confirm results at a median of 26 months follow-up that led to the approval of Femara in the adjuvant setting. With the long-term follow-up in the analysis conducted more than 10 years after the start of the study, adverse events for Femara and tamoxifen were found to be consistent with the known safety profiles of both drugs.

Femara is contraindicated in women of premenopausal status. 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, arthritis, stroke, heart attack and endometrial cancer.

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 hormone receptor-positive or hormone receptor-unknown breast cancer that has spread to another part of the body (metastatic cancer).

For more information about Femara, please talk to your doctor and visit www.Femara.com or www.NovartisOncology.com.

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.

Femara is a once-daily, convenient prescription tablet.

For more information about Femara or to see the full Novartis privacy policy, visit online at www.femara.com or call toll-free 1-866-44-FEMARA (1-866-443-3627).