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**Side Effects of New Drug for High-Risk Breast Cancer Are Manageable**

DURHAM, N.C., August 2 - Some practical recommendations can aid in managing adverse reactions to lapatinib (Tykerb)—a new drug that improves the outcomes of treatment for breast cancers with certain mutations linked to a high risk of recurrence—according to an article in the July issue of "The Oncologist."

"Lapatinib is associated with some toxicity, but for the most part it is highly manageable," comments Dr. Beverly Moy of Massachusetts General Hospital Cancer Center, Boston, who coauthored the new article along with Dr. Paul E. Goss. "We're hoping to provide some guidance in managing the unique side effects of this medication."

Lapatinib is one of a new class of drugs called "oral dual kinase inhibitors," which block the ErbB-1 and ErbB-2 receptors. Around 20 to 30 percent of breast cancers have mutations leading to high expression and activation of ErbB-1 and ErbB-2, which are associated with an increased risk that the cancer will recur after treatment. Previous studies have shown that lapatinib treatment to block these receptors improves outcomes for women with advanced (metastatic) "ErbB-2-overexpressing" breast cancers. Lapatinib was approved by the U.S. Food and Drug Administration in March 2007.

Drs. Moy and Goss provide an overview of the considerable data on the potential adverse effects of lapatinib. Diarrhea and skin rash are the most common side effects, followed by nausea and fatigue. Fortunately, most of these side effects are relatively mild—in one study, less than four percent of lapatinib-related adverse events were rated severe. Very few disabling or fatal reactions to lapatinib have been reported.

About 30 percent of patients develop a rash on areas such as the face, chest, and back—similar to the folliculitis that may be caused by shaving. A similar rash occurs in patients treated with other drugs that block the ErbB-1 receptor, such as erlotinib (Tarceva)—a new drug used to treat advanced lung or pancreatic cancer.

The skin rash may even have implications for the outcomes of lapatinib treatment. One recent study suggested that the erlotinib-related rash may be a sign of treatment effectiveness—patients who developed a rash during erlotinib treatment survived longer than those without a rash. Preliminary data suggest that a rash may also be a sign of improved outcomes in patients receiving lapatinib for other types of cancer. "With lapatinib, there is no definitive proof that a rash is associated with the response to treatment for breast cancer," says Dr. Moy. "However, it's a provocative finding that certainly warrants further study."

In the absence of research-based guidelines, Drs. Moy and Goss offer some practical recommendations for the management of lapatinib-related adverse effects. The skin rash usually clears up during treatment—topical medications, or sometimes antibiotics, may be helpful if needed. Diarrhea can usually be managed through diet changes and standard medications. In both cases, the side effects are usually relatively mild; treatment may help avoid the need to interrupt or stop treatment with lapatinib.

Although some other drugs that block the ErbB-2 receptor have been linked to toxic effects on the heart, such cardiac toxicity appears relatively uncommon with lapatinib. Still, the authors suggest it might be a good idea to assess heart function before starting lapatinib treatment.

"We hope that these practical recommendations will help to control lapatinib side effects for the vast majority of patients," adds Dr. Moy. "It would be great to be able to control the most common side effects of diarrhea and rash so that patients with advanced breast cancer can continue treatment with this effective medication."

The new article, entitled "Lapatinib-Associated Toxicity and Practical Management Recommendations," is available online at <http://theoncologist.alphamedpress.org> and in print in the July issue of "The Oncologist."

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