

Glaxo seeks OK to expand breast cancer drug use

April 1 2009, By LINDA A. JOHNSON, Associated Press Writer

(AP) -- GlaxoSmithKline PLC on Wednesday applied for approval in the U.S. and Europe to sell an existing breast-cancer drug as a first-line treatment.

The British pharmaceutical company's Tykerb was approved here two years ago as part of a treatment for most women with advanced <u>breast</u> <u>cancer</u> that wasn't stopped after <u>chemotherapy</u> and other drugs. It's also been approved for that use in the 27 European Union countries and several others.

Tykerb had sales of \$189 million last year. Approval as an initial treatment likely would boost that sharply.

Tykerb, a pill that is more targeted than chemotherapy, is designed for women whose breast cancer is hormone sensitive, meaning it is fueled by the <u>estrogen</u> their body makes.

GlaxoSmithKline is seeking to market Tykerb as an initial treatment for hormone-sensitive breast cancer that has spread. About two-thirds of breast cancers are hormone sensitive.

If approved, Tykerb - known as Tyverb in Europe - will be used along with another drug that prevents hormones from making cancer cells multiply.

Normally women with advanced, hormone-sensitive breast cancer get a



hormonal drug - one that blocks estrogen from attaching to cell receptors and making cancer cells multiply - along with chemotherapy.

But chemotherapy medicines, which often are given intravenously, attack healthy cells as well as cancerous ones, causing nasty side effects such as <u>vomiting</u> and hair loss that limit how much of those medicines can be given.

In addition, "at a certain point in time, the cells don't respond anymore to the hormonal therapy," said Dr. Debasish Roychowdhury, head of oncology medicines development at GlaxoSmithKline.

Tykerb works by attaching to two other cell receptors and ultimately making the cells die or stop multiplying. It targets cancer cells more than healthy ones, Roychowdhury said. That can mean fewer side effects, although Tykerb can damage the liver and harm a fetus.

A study GlaxoSmithKline presented in December found that in postmenopausal women with advanced breast cancer Tykerb, along with the hormonal treatment Femara, increased average survival without the cancer worsening from about three months to just over eight months, compared to women who got Femara pills alone.

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