ASCO Guideline Update Recommends Tamoxifen for Up to 10 Years for Women With Non-Metastatic Hormone Receptor Positive Breast Cancer

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The American Society of Clinical Oncology (ASCO) today issued an update to its clinical practice guideline on the use of adjuvant endocrine therapy for women with stages I-III hormone receptor positive breast cancer.

The update reflects new data on the duration of tamoxifen treatment from five studies reviewed since ASCO’s 2010 update to this guideline. In the two largest randomized studies that had the longest follow-up, women who took tamoxifen for 10 years had a breast cancer survival advantage, as well as lower risks of breast cancer recurrence and contralateral breast cancer, compared to those who took tamoxifen for five years.

“Tamoxifen taken for five years has been the standard adjuvant endocrine treatment for decades, but we now have evidence to recommend up to 10 years of tamoxifen for women with hormone receptor-positive breast cancer,” said Harold J. Burstein, MD, PhD, co-chair of ASCO’s Expert Panel that wrote the guideline update. “Postmenopausal women also have the option of taking an aromatase inhibitor as an alternative to tamoxifen or in sequence after tamoxifen. Aromatase inhibitors are not recommended for premenopausal women.”

Hormone receptor-positive (HR+) breast cancer is the most common type of breast cancer worldwide. About 60 percent to 75 percent of women with breast cancer have estrogen receptor-positive (ER+) breast cancer and 65 percent of these cancers are also progesterone receptor-positive (PgR+). Adjuvant endocrine therapy is highly effective and appropriate for nearly all women with ER- and/or PgR-positive tumors.
To develop this clinical practice guideline, an ASCO Expert Panel conducted a formal systematic review of relevant medical literature. Two randomized trials on extended durations of tamoxifen—one published and the other presented at the 2013 ASCO Annual Meeting—provided evidence for the new recommendation. There has been no new evidence on extended durations of aromatase inhibitors since the previous guideline update.

Key guideline recommendations:

- Women diagnosed with hormone receptor-positive breast cancer who are pre-/peri-menopausal should be offered adjuvant endocrine therapy with tamoxifen for 5 years, after which they should receive additional therapy based on menopausal status. If premenopausal, they should be offered continued tamoxifen for a total duration of 10 years. If postmenopausal, they should be offered continued tamoxifen for a total duration of 10 years or an aromatase inhibitor (AI) for a total duration of up to 10 years of adjuvant endocrine therapy.

- Women diagnosed with hormone receptor-positive breast cancer who are postmenopausal should be offered adjuvant endocrine therapy with one of the following options: tamoxifen for 10 years; an AI for 5 years; tamoxifen for 5 years, then switching to an AI for up to 5 years; or tamoxifen for 2-3 years and switching to an AI for up to 5 years.

- Women who are postmenopausal and are intolerant of either tamoxifen or an AI should be offered the alternative type of adjuvant endocrine therapy. If women have received an AI, but discontinued treatment at less than 5 years, they may be offered tamoxifen for a total of 5 years. If women have received tamoxifen for 2-3 years, they should be offered an AI for up to 5 years, for a total duration of up to 7-8 years of adjuvant endocrine therapy.

The guideline also discusses issues clinicians face in communicating with women about taking adjuvant endocrine therapy for extended periods of time.

"It is important for clinicians and patients to discuss the trade-offs between potential risks of side effects and potential benefits of taking adjuvant endocrine therapy for up to 10 years," said Jennifer Griggs, MD, MPH, co-chair of the ASCO Expert Panel. "Many women taking adjuvant tamoxifen experience side effects, and these appear to persist with longer duration. However, the trials did not find any new or unexpected side effects."

The guideline, *Adjuvant Endocrine Therapy for Women with Hormone Receptor-Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Focused Update*, was published today in the *Journal of Clinical Oncology*.

Information explaining these recommendations and what they mean for patients is available at [www.cancer.net/recommendations](http://www.cancer.net/recommendations). The guideline will be available at [http://www.asco.org/guidelines/breast-cancer](http://www.asco.org/guidelines/breast-cancer), along with supplementary materials.

**About ASCO:**
Founded in 1964, the American Society of Clinical Oncology (ASCO) is the world’s leading professional organization representing physicians who care for people with cancer. With more than 35,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds groundbreaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit asco.org. Patient-oriented cancer information is available at Cancer.Net.