Breast Cancer Guidelines Confirm Central Role of 'Switch Strategy'; Recommendations of St Gallen Panel Support Exemestane Indication

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(BUSINESS WIRE)--Guidelines from the 2007 St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer, published today in the Annals of Oncology (http://annonc.oxfordjournals.org), confirm the value of switching from tamoxifen to an aromatase inhibitor (AI), such as exemestane, for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.i

Approximately 360,000 women in Europe are diagnosed with breast cancer each year. With up to two thirds of breast cancers requiring the hormone estrogen to grow, medicines such as exemestane are crucial for women affected by this disease, because they work by interfering with the supply of estrogen to the cancer and preventing it from growing. Switching from tamoxifen to exemestane has the potential to save lives among women diagnosed with hormone receptor positive early breast cancer.ii

The St Gallen guidelines are the consensus of breast cancer experts from around the world, who have assessed and recommended optimal treatment strategies for this disease, which affects the lives of thousands of women and their families.

“Guidelines are essential for physicians, as they ensure we are up to date with the latest recommendations for patient care,” said Professor Charles Coombes, Head, Department of Oncology, Imperial College, London. “The St Gallen guidelines have confirmed the value of starting treatment with tamoxifen then switching to an aromatase inhibitor, enabling women to benefit from the advantages of both medicines. Exemestane, one of the aromatase inhibitors, has been proven to offer an overall survival benefit in the

switch setting, and these latest guidelines confirm to physicians that we should continue to use it in this way to offer patients the very best care."

In hormone receptor positive breast cancer, the St Gallen panel expressed a clear preference for switching patients from tamoxifen to an AI, such as exemestane, which means more patients can benefit from exemestane's proven results in extending lives.

The guidelines follow publication of the Intergroup Exemestane Study (IES) in The Lancet earlier this year, which showed an overall survival benefit for women who switched from tamoxifen to exemestane, the only AI to have demonstrated overall survival in a single, double-blind trial.ii The IES, which randomized 4,724 patients across 37 countries, demonstrated that postmenopausal women1 with early breast cancer, who switched to exemestane after 2-3 years of tamoxifen, experienced a 17% reduction in the risk of death compared to those who stayed on tamoxifen for the full 5 years of therapy.ii Exemestane was the first AI to receive approval in the switch setting.

Professor Coombes, who was lead investigator of the IES, continued, "The IES results, and now the St Gallen guidelines, confirm that switching to exemestane rather than staying on tamoxifen gives women an improved chance of survival. Furthermore, switching to exemestane has also been proven to have no significant adverse effect on quality of life compared to tamoxifen alone,iii making it a good all-round option for women."

About exemestane iv

Exemestane is currently indicated for the adjuvant treatment of postmenopausal women with estrogen receptor positive invasive early breast cancer who have received 2-3 years of tamoxifen and are switched to exemestane for the completion of a total of 5 consecutive years of adjuvant hormonal therapy. Exemestane is also indicated for the treatment of advanced breast cancer in women with natural or induced postmenopausal states, whose disease has progressed following anti-estrogen therapy.

Exemestane should not be used in women who are premenopausal, are nursing or pregnant, have a known hypersensitivity to the drug, or are taking estrogen-containing agents. Exemestane should be used cautiously with drugs that are metabolised via CYP3A4 and have a narrow therapeutic window.

Exemestane was generally well tolerated across all clinical studies; undesirable effects were usually mild to moderate. The withdrawal rate due to adverse events in studies was 6.3% in patients with early breast cancer receiving adjuvant treatment with exemestane following initial adjuvant tamoxifen therapy and 2.8% in the overall patient population

with advanced breast cancer receiving the standard dose of 25 mg. In patients with early breast cancer the most commonly reported adverse reactions were hot flushes (22%), arthralgia (17%) and fatigue (17%). In patients with advanced breast cancer the most commonly reported adverse reactions were hot flushes (14%) and nausea (12%). Most adverse reactions can be attributed to the normal pharmacological consequences of estrogen deprivation (e.g. hot flushes).

1 Women with estrogen receptor positive or unknown status of disease.

i Goldhirsch A, Wood WC, Gelber RD et al. Progress and promise: highlights of the international expert consensus on the primary therapy of early breast cancer 2007. Ann Oncol 2007; 18: 1133-1144.

ii Coombes RC et al. Survival and safety of exemestane versus tamoxifen after 2-3 years' tamoxifen treatment (Intergroup Exemestane Study): a randomised controlled trial. Lancet. 2007 Feb 17;369(9561):559-70

iii Fallowfield LJ et al. Quality of Life in the Intergroup Exemestane Study (IES) – a Randomized Trial of Exemestane versus Continued Tamoxifen after 2-3 years of Tamoxifen in Postmenopausal Women with Primary Breast Cancer. Journal of Clinical Oncology. Vol 24, No 6, Feb 20, 2006

iv Exemestane prescribing information (Summary of Product Characteristics dated 24 August 2005)

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