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Eisai subsidiary announces cancer trial results

January 15, 2013 | News | By BioSpectrum Bureau



Singapore:Ã?Â Eisai announced the preliminary results of its global phase III study (Study FAR 131, MORAb-003-004) of farletuzumab (MORAb-003), an investigational compound under development at its US subsidiary, Morphotek, in patients with platinum-sensitive epithelial ovarian cancer in first relapse.

The study was a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparative study of 1,100 patients with platinum-sensitive epithelial ovarian cancer in first relapse. The patients received standard-of-care therapy (carboplatin and a taxane) in combination with doses of either 1.25 mg/kg of farletuzumab, 2.5 mg/kg of farletuzumab, or placebo.

Preliminary results showed that the trial did not meet the pre-specified statistical criteria for significant progression-free survival (PFS), the study's primary endpoint. The post hoc exploratory analysis showed, however, a trend toward improved PFS in some patient subsets and further analysis is ongoing.

The preliminary safety analysis indicated that the most commonly reported adverse events were those known to be associated with the study chemotherapy agents. Additionally, some immune-mediated events were observed with farletuzumab. After further analysis of these clinical results, the company will determine a new development strategy based on discussion with external experts and the relevant health authorities.

Eisai remains committed to understanding the potential clinical benefits of farletuzumab in order to further contribute to patients with cancer, including patients with recurrent ovarian cancer, and their families. Ã?Â