

Liposomal Doxorubicin Earns Full Approval for Treatment of Ovarian Cancer

The US Food and Drug Administration (FDA) has granted full approval to liposomal doxorubicin (Doxil) for the treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy. As a result of the full approval, the product label for liposomal doxorubicin has been updated to include survival, time to disease progression, and tumor response rate data from a randomized phase III clinical study.

Under accelerated approval, liposomal doxorubicin was indicated for the treatment of metastatic ovarian cancer in patients with disease that was refractory to both paclitaxel- and platinum-based chemotherapy regimens. This approval was based on tumor response rates from three

phase II studies. A randomized phase III clinical study formally demonstrated the drug's clinical benefit in patients with relapsed ovarian cancer.

"The phase III data provide evidence of the product's clinical benefit for patients with relapsed ovarian cancer," commented Alan N. Gordon, MD, of the University of Arizona School of Medicine and Arizona Gynecologic Oncology in Phoenix, and lead author of the phase III study, known as DOXIL Study 30-49.

In this randomized, multicenter, open-label, phase III study, 474 patients with recurrent epithelial ovarian cancer were randomly assigned to receive either liposomal doxorubicin (50 mg/m² every 28 days) or topotecan (Hycamtin; 1.5

mg/m²/day for 5 consecutive days every 21 days). A total of 239 patients received liposomal doxorubicin; 235 patients received topotecan. The primary endpoint, time to disease progression after starting therapy, was comparable for the two treatment groups. The median time to disease progression was 4.1 months for the liposomal doxorubicin group and 4.2 months for the topotecan group ($P = 0.617$). The overall median survival was 14.4 months for patients treated with liposomal doxorubicin and 13.7 months for patients treated with topotecan ($P = 0.05$). The P value was not adjusted for multiple comparisons. The overall tumor response rate was 19.7% for doxorubicin-treated patients and 17.0% for topotecan-treated patients.