A tale of the two PEGylated liposomal doxorubicins

Dear editor

We are writing this letter in response to the article “Outcomes analysis of an alternative formulation of PEGylated liposomal doxorubicin in recurrent epithelial ovarian carcinoma during the drug shortage era” by Berger et al and published in August 2014.1 This paper is one of the earliest reports of the outcome of using Lipodox® available in the Western medical literature.

There are two PEGylated liposomal doxorubicin formulations, with the brand names Lipodox and Lipo-Dox®. Lipodox is manufactured by Sun Pharma and has been approved by the US Food and Drug Administration as a generic of Doxil® since February 4, 2013.2 Lipo-Dox is manufactured by TTY Biopharm, and has a lipid formulation different to that of Doxil and has a longer half-life;3 it has been sold in Taiwan and many Asian countries since 1998, and is probably the alternative formulation referenced in the paper by Berger et al.1 Berger et al incorrectly referenced two Asian ovarian cancer trials for efficacy and survival data for Lipodox, and we need to set the record straight that the Taiwanese trial used TTY Biopharm Lipo-Dox,4 and that the Japanese trial most likely used the originator Doxil.5 Another smaller study using single-agent TTY Biopharm Lipo-Dox in patients with ovarian cancer refractory to both cisplatin and paclitaxel produced efficacy similar to that reported by Chou et al6 but with no serious toxicity because of a slightly lower dose (see Table 1).

Disclosure

The authors report no conflicts of interest in this communication.

Table 1 Clinical trials reporting single-agent liposomal doxorubicin therapy for refractory ovarian cancer, with dosage, response, survival, and toxicity information

<table>
<thead>
<tr>
<th>Ovarian cancer</th>
<th>Patients (n)</th>
<th>Dose/4 weeks</th>
<th>ORR</th>
<th>PFS/OS months</th>
<th>Grade 3-4 toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berger et al1 Lipodox® Recurrent</td>
<td>18</td>
<td>30 mg/m²</td>
<td>0</td>
<td>2.8/NR</td>
<td>Neutropenia 5.6%</td>
</tr>
<tr>
<td>Lin et al6 Lipo-Dox® CDDP-resistant and paclitaxel-resistant</td>
<td>18</td>
<td>40 mg/m²</td>
<td>27.8%, three CR, two PR</td>
<td>3.5/12</td>
<td>0</td>
</tr>
<tr>
<td>Chou et al4 Lipo-Dox Resistant/refractory</td>
<td>29</td>
<td>45 mg/m²</td>
<td>23%, one CR, 5.4/13.8</td>
<td>Neutropenia 12%</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CR, complete response; PR, partial response; ORR, overall response rate; PFS, progression-free survival; OS, overall survival; NR, not reached; CDDP, diaminedichloroplatinum(II).
Chou et al

References