Erratum

Erratum to “NCCAM/NCI Phase 1 Study of Mistletoe Extract and Gemcitabine in Patients with Advanced Solid Tumors”

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Received 22 November 2013; Accepted 18 December 2013; Published 12 February 2014

There were several modifications in the paper. They are shown as follows.

Page 1, Abstract: the sentence in the abstract “Dose limiting toxicities (DLT) were grade (G) 3 nonhematologic and G4 hematologic events” should read “… and G4 hematologic events related to platelets and granulocytes only.”

“GEM 1380 mg/m^2 and mistletoe 250 mg combined were the MTD” should read “GEM 1300 mg/m^2 and mistletoe 250 mg combined were the MTD.”

Page 2, Introduction: “While ML antibodies were absent in patients without adverse effects, …” should read “While ML antibodies type IgE were absent in patients ….”

Page 2, Materials and Methods: “A whole plant mistletoe extract (HELIXOR Apis (A), growing on fir trees)” should read “A whole plant mistletoe extract (Helixor A (Abietis), growing on fir trees).”

Page 2, Materials and Methods: “Helixor, GmbH, Rosenfeld” should read “Helixor Heilmittel GmbH & Co. KG, Rosenfeld.”

Page 3, Study Design and Outcomes: the sentence “… was administered with gemcitabine in 20% dose increments per dose level (900, 1080, 1380, and 1560 mg/m^2 …)” should read “… (900, 1080, 1300, and 1560 mg/m^2 …).”

Page 4, Results: Maximum Tolerated Dose and Dose Limiting Toxicities. The last sentence in this paragraph should read as follows: Thus, we achieved the MTD at dose level 8 (gemcitabine 1300 mg/m^2 and mistletoe 250 mg).

Paragraph 3.4. “Three study participants experienced individual DLTs at dose level 9 (gemcitabine 1560 mg/m^2 with 250 mg daily of mistletoe). These included grade 3 cellulitis at the mistletoe injection site, grade 4 acute renal failure, and grade 4 neutropenia” should read “… and grade 4 thrombocytopenia.”

Page 8, Discussion: the sentence “The MTD for the gemcitabine/mistletoe combination in this study was gemcitabine 1380 mg/m^2 …” should read “The MTD for the gemcitabine/mistletoe combination in this study was gemcitabine 1300 mg/m^2 ….”
Table 4: Dose limiting toxicities by dose level.

<table>
<thead>
<tr>
<th>Stage I (fixed GEM dose of 750 mg/m²)</th>
<th>Stage II (fixed mistletoe dose, established in stage I)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level</td>
<td>N</td>
</tr>
<tr>
<td>(1) (escalating daily mistletoe injections, reaching: 20 mg/day)</td>
<td>3</td>
</tr>
<tr>
<td>(2) (escalating daily mistletoe injections, reaching: 50 mg/day)</td>
<td>3</td>
</tr>
<tr>
<td>(3) (escalating daily mistletoe injections, reaching: 100 mg/day)</td>
<td>3</td>
</tr>
<tr>
<td>(4) (escalating daily mistletoe injections, reaching: 200 mg/day)</td>
<td>6</td>
</tr>
<tr>
<td>(5) (escalating daily mistletoe injections, reaching: 250 mg/day)</td>
<td>5</td>
</tr>
</tbody>
</table>

*Per study protocol, this level represents the maximum tolerated dose, as 3 DLT’s were observed in the subsequent dose level.

Page 8, Table 4: Dose limiting toxicities by dose level. “Level/dosage 8 (250 mg/day mistletoe; 1380 mg/m² GEM on day 1/8 of 3-week cycle)” should read “Level/dosage 8 (250 mg/day mistletoe; 1300 mg/m² GEM on day 1/8 of 3-week cycle).”

Page 9, Discussion: the sentence “None of the study patients developed febrile neutropenia even at the highest gemcitabine dose of 1650 mg/m²” should read “None of the study patients developed febrile neutropenia even at the highest gemcitabine dose of 1560 mg/m².”

Page 9, Conclusion: the sentence “the MTD was gemcitabine 1380 mg/m² weekly …” should read “the MTD was gemcitabine 1300 mg/m² weekly …”.

Page 10, Acknowledgments: the second sentence should read: They greatly appreciate … the support of Drs. Dietrich Schlodder and Jörg Schierholz.

The sentence “… as well as Sabine Rieger from Helixor GmbH” should read “… as well as Sabine Rieger from Helixor Heilmittel GmbH & Co. KG.”

The sentence “Mistletoe extract (Helixor A) was provided by Helixor GmbH, Rosenfeld, …” should read “Mistletoe extract (Helixor A) was provided by Helixor Heilmittel GmbH & Co. KG, Rosenfeld, ….”