

Erratum

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

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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/m² and mistletoe 250 mg combined were the MTD” should read “GEM 1300 mg/m² 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/m² . . .)” should read “. . . (900, 1080, 1300, and 1560 mg/m² . . .).”

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/m² and mistletoe 250 mg).

Paragraph 3.4. “Three study participants experienced individual DLTs at dose level 9 (*gemcitabine* 1560 mg/m² 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/m² . . .” should read “The MTD for the *gemcitabine/mistletoe* combination in this study was *gemcitabine* 1300 mg/m² . . .”

TABLE 4: Dose limiting toxicities by dose level.

Stage I (fixed GEM dose of 750 mg/m ²)			Stage II (fixed mistletoe dose, established in stage I)			
Level	N	DLT	Level/dosage	N	DLT	Action taken per protocol
(1) (escalating daily mistletoe injections, reaching: 20 mg/day)	3	None	(6) (250 mg/day mistletoe; 900 mg/m ² GEM on day 1/8 of 3-week cycle)	7	Grade 4 neutropenia	Dose reduced; enrolled 3 more patients at this dose level.
(2) (escalating daily mistletoe injections, reaching: 50 mg/day)	3	None	(7) (250 mg/day mistletoe; 1080 mg/m ² GEM on day 1/8 of 3-week cycle)	7	Grade 4 thrombocytopenia	Dose reduced; enrolled 3 more patients at this dose level.
(3) (escalating daily mistletoe injections, reaching: 100 mg/day)	3	None	(8)* (250 mg/day mistletoe; 1300 mg/m ² GEM on day 1/8 of 3-week cycle)	6	None	N/A
(4) (escalating daily mistletoe injections, reaching: 200 mg/day)	6	None	(9) (250 mg/day mistletoe; 1560 mg/m ² GEM on day 1/8 of 3-week cycle)	4	Grade 3 cellulitis ^a ; grade 4 acute renal failure ^b ; grade 4: thrombocytopenia ^c	^a mistletoe therapy withheld; patient rechallenged and developed hypersensitivity reaction. Mistletoe discontinued; ^b Pt. treated for renal failure and subsequently withdrawn from study; ^c Pt. hospitalized d/t other AE; <i>Maximum tolerated dose reached per protocol.</i>
(5) (escalating daily mistletoe injections, reaching: 250 mg/day)	5	None				

* 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, ...*"