Reviewer's report

Title: Phase II Assessment of Talabostat and Cisplatin in Second-Line Stage IV Melanoma

Version: 1 Date: 30 January 2009

Reviewer: Hong-Suk Song

Reviewer's report:

Minor Essential Revisions are required.
1) Title: Phase II Assessment of Talabostat and Cisplatin in Second-Line Stage IV Melanoma # Phase II assessment of talabostat and cisplatin in second-line stage IV melanoma
2) Abstract: Conclusion # Conclusions
3) Introduction: Introduction # Background
4) Introduction: chemotherapy combination # combination chemotherapy
5) Introduction: dacarbazine # dacarbazine
6) Introduction: dicarbazine # dacarbazine
7) Introduction: biochemotherapeutic agents interferon-alpha # biochemotherapeutic agents, interferon-alpha
8) Statistical analysis: The Evaluable Population # The evaluable population
9) Statistical analysis: Intent-to-Treat (ITT) Population # intention-to-treat (ITT) population
10) Statistical analysis: The Safety Population # The safety population
11) Statistical analysis: The ITT Population # The ITT population
12) Results: ITT and Evaluable populations # ITT and evaluable populations
13) Results: Table 1, Table 2,...Table 8 # Table 1, Table 2,...Table 8 (BOLD)
14) Efficacy: ITT Population # ITT population
15) Efficacy: in the Evaluable Population # in the evaluable population
16) Safety: the Safety Population # the safety population
17) Safety: Grade 3 or Grade 4 # grade 3 or grade 4
18) Safety: Cycle 6 # cycle 6
19) Safety: in Cycle 1 and/or 2 # in cycle 1 and/or 2
20) Discussion: the Evaluable Population # the evaluable population
21) Discussion: ITT Population # ITT population
22) Discussion: a Grade 2 or a Grade 3 # a grade 2 or a grade 3
23) Discussion: with Phase 1 studies # with phase 1 studies
24) Discussion: of Grade 4 neutropenia # of grade 4 neutropenia
25) Discussion: neutropenia, Grade 3 or Grade 4 anemia # neutropenia, grade 3 or grade 4 anemia
26) References: 1…. 33. # [1] … [33]
28) Ref. 6: Lienard D # Liénard D
29) Ref. 8: Nanni O. # Nanni O, Italian Melanoma Intergroup.
30) Ref. 10: (abstract) # (abstract 2849)
31) Ref. 17: Saiag P # Saïag P
32) Ref. 19: Characterization of Innate Effector Cells Involved in the Anti-Tumor Activity of Talabostat (PT-100). # Characterization of innate effector cells involved in the anti-tumor activity of talabostat (PT-100).
33) Ref. 20: T-cell Independent Antitumor Activity of Talabostat (PT-100) as a Single Agent and in Combination with Chemotherapy in Mice. # T-cell independent antitumor activity of talabostat (PT-100) as a single agent and in combination with chemotherapy in mice.
34) Ref. 30: Phase 1 Rising Multiple-Dose Study of Talabostat (PT-100) in Healthy Subjects. # Phase 1 rising multiple-dose study of talabostat (PT-100) in healthy subjects.
35) Ref. 31: Phase I Study of Talabostat and Rituximab in Patients with Indolent Non-Hodgkin’s Lymphoma with Primary Resistance to or Progression Following Rituximab. # Phase I study of talabostat and rituximab in patients with indolent non-Hodgkin’s lymphoma with primary resistance to or progression following rituximab.
31) Table 1: ITT = Intention-to-Treat # ITT = intention-to-treat
32) Table 2: Overall Objective Response Rate # Overall objective response rate
33) Table 4: ----Time to PD or Death (days)---- Median (95% CI) # Median (95% CI), days
34) Table 5: ---Time to Death (days)--- Analysis with censoring of patients began a new therapy median (95% CI) # Analysis with censoring of patients began a new therapy median (95% CI), days
35) Table 6: Adverse events (safety population; n=74). N (%) patients # Adverse events (safety population; n=74), n (%) of patients
36) Table 7: Vision-Blurred # Vision-blurred

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interest