Initial efficacy and safety of RP1 + nivolumab in patients with anti–PD1–failed melanoma from the ongoing phase 1/2 IGNITE study

Barbora Chmielowski1, Mohammed M. Milhem2, Joseph J. Sacco3, Tawnya Lynn Bowles4, Katy K. Tsa5, Gino K. In6, Eva Muñoz-Couselo7, Ari M. VanderWalde8, Jason Alan Chesney9, Judith Michels10, Adel Samson11, Georgia M. Beasley12, Dirk Schadendorf13, Fade Mahmoud14, Michael K. Wong15, Trisha M. Wise-Drappe16, Junhong Zhu17, Praveen K. Bommareddy18, Jeanne W. Hoi19, Mark R. Middleton20

Abstract: 9509

Objective response rates

- The overall objective response rate (ORR) was 37.4% (95% CI, 34.4%–40.4%) in all subgroups analyzed. The ORR was 36.0% (95% CI, 31.9%–40.1%) in patients who are PD-L1 negative, 35.3% (95% CI, 29.4%–41.2%) in patients with unknown PD-L1, and 37.5% (95% CI, 32.1%–42.9%) in patients who are PD-L1 positive.

Response kinetics for injected and un.injected lesions

- Systemic effects across the body detected in >90% of patients have been seen. In patients where only a small minority of lesions were injected, the responses of noninjected lesions were seen. Furthermore, patients who had lesions that were not injected showed similar responses, including for durability of response.

Influence of baseline tumor PD-L1 & BRAF mutation status

- Most patients were BRAF wild type, and were expected to be the best response for therapy. However, patients with both BRAF mutations and PD-L1 positivity may have a potential for increased response.

Conclusion

- RP1 treatment is associated with sustained clinical benefit for patients who have failed anti–PD1 therapy.

Results: Efficacy & Safety

- The overall objective response rate (ORR) was 37.4% (95% CI, 34.4%–40.4%) in all subgroups analyzed.

- ORR was 36.0% (95% CI, 31.9%–40.1%) in patients who are PD-L1 negative, 35.3% (95% CI, 29.4%–41.2%) in patients with unknown PD-L1, and 37.5% (95% CI, 32.1%–42.9%) in patients who are PD-L1 positive.

- Responses were seen irrespective of stage of disease, including complete responses in stage IV disease.

- Durable responses are observed in both PD-L1 negative as well as PD-L1 positive patients.

- Progression-free and overall survival are promising, including when broken down by prognostic factors, and injection/lesion cohorts.

- There was no impact of whether or not all lesions were injected with RP1.

- Diarrhea was the most frequent treatment-related adverse event, occurring in 15 (22.2%) patients. Other treatment-related adverse events included nausea (14.1%), chills (14.1%), and headache (14.1%).