Interim Analysis of Phase 2 Results for Cemiplimab in Patients with Metastatic Basal Cell Carcinoma (mBCC) who Progressed on or are Intolerant to Hedgehog Inhibitors (HHIs)

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Synopsis

- Cemiplimab was an objective response rate (ORR) of 31% in patients with metastatic cutaneous basal cell carcinoma (mBCC).
- The median time to first response was 3.2 months, and the median duration of response was 8.3 months.
- The safety profile of cemiplimab is consistent with previous reports of cemiplimab.
- Among responders, median time to response per ICR was 3.2 months (range, 1.5–8.0).
- The disease control rate was 79% (95% CI, 67–90%).
- The durable disease control rate was 44% (95% CI, 37–50%).
- The median Kaplan-Meier estimate of OS was 25.7 months (95% CI, 19.5–NE).
- The median Kaplan-Meier estimate of PFS was 8.3 months (95% CI, 3.6–19.5).

Methods

- This is a Phase 2, non-randomized, multi-center study of cemiplimab in patients with metastatic BCC (mBCC) or locally advanced BCC (laBCC) who progressed on or are intolerant to previous HHI therapy; the safety profile was acceptable and laBCC after treatment with HHI therapy; the safety profile was acceptable and tolerable.
- Patients followed by the ICR were censored and an independent radiology review committee assessed for objective response per investigator.
- The data cut-off date for the results reported here was February 17, 2020.

Results

- Among patients who received cemiplimab, 305 patients were randomized to cemiplimab (51% mBCC, 49% laBCC). Cemiplimab therapy consisted of five 9-week treatment cycles followed by four 12-week cycles.
- Clinical activity included objective complete response (CR) or partial response (PR), defined as the proportion of patients with complete response, partial response, stable disease, or non-partial response.
- The median Kaplan-Meier estimation of OS was 25.7 months (95% CI, 19.5–NE).
- The median Kaplan-Meier estimation of PFS was 8.3 months (95% CI, 3.6–19.5).