SKIN CANCER (OTHER THAN MELANOMA)

LONG-TERM EFFICACY AND SAFETY OF BEXAROTENE FOR JAPANESE PATIENTS WITH CTCL

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Introduction: We have already reported the efficacy, safety and tolerability of bexarotene for Japanese patients with CTCL as a result of a phase I/II clinical study (B-1101 trial).

Objective: We conducted a multicenter, open-label, single-arm phase II clinical trial (B-1201 trial) as a long-term study after B-1101 trial, in order to investigate long-term efficacy and safety of bexarotene for Japanese patients with CTCL.

Methods: B-1201 trial was planned as a long-term follow-up study after the previous B-1101 trial between August 1, 2012 and January 10, 2017. At the end of week 24 visit in B-1101 trial, patients were eligible to continue bexarotene for up to four additional years.

Results: ORR was 53.8% (95% CI, 25.1-80.8). The median TTR (time to treatment) was 58 days, ranged from 27 to 168 days. The median treatment duration was 380 days, ranged from 33 to 1,674 days. The median DOR (duration of response) could not be reached during the study period. The longest DOR reached 1,618 days at the end of the B-1201 trial. Nine patients (56.3%) of the FAS population experienced dose reduction of bexarotene. Common drug-related adverse events included hypothyroidism (93.8%), hypertriglyceridemia (81.3%), hypercholesterolemia (81.3%), leukopenia (68.8%) and neutropenia (56.3%) in the

FAS population. DLT was presented in 5 (38.5%) out of the 13 patients of the 300mg/m2 cohort. Of the five patients, four and one patients developed grade 3 neutropenia and grade 4 hypertriglyceridemia, respectively. All DLTs recovered by discontinuation of bexarotene. None of the five patients had discontinued this trial because of DLT.

Conclusions: B-1201 trial showed a long-term safety and efficacy of oral bexarotene for Japanese patients with CTCL despite frequent dose reduction.