This study aimed to obtain post-marketing data on the efficacy of nivolumab in Japanese patients with advanced melanoma.

METHODS

This prospective observational study was performed in patients with unresectable or metastatic melanoma. The patients were treated with nivolumab at a dose of 2 mg/kg every 3 weeks (Q3W) or 3 mg/kg every 2 weeks (Q2W).

The primary endpoints were response rate (RR) and overall survival (OS).

The secondary endpoints were progression-free survival (PFS) and RR according to the immune-related response criteria (irRECIST).

In addition, biomarker analyses were planned at specific time points (before treatment and at 7, 13, 19, and 25 weeks).

RESULTS

Figure 1. Progression-free survival (PFS) in all patients

The median PFS was 2.56 months and the 1-year PFS was 19%. No. of Patients 125

BRAF status

Table 2. Best response in all patients

CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; NS, not evaluable; ORR, objective response rate; DCR, disease control rate.

• We enrolled 125 patients from 22 institutions.

• Mucosal melanoma was the most common clinical subtype, followed by AJM, NM, and LMM.

• irRECIST evaluation showed an ORR of 17.6%.

• Subgroup analysis according to the clinical subtype indicated that the response rate of patients with SM and ALM was lower than that of patients with other clinical subtypes.

• Patients with BRAF wild-type melanoma, PS 0, and who received nivolumab as first-line treatment showed better response rates, but the difference in the response rates was not statistically significant.

• Subgroup analysis indicated that the clinical subtype did not affect PFS.

• The patients with BRAF wild-type melanoma, treated with nivolumab 3 mg/kg, or those receiving nivolumab as a first-line treatment showed better PFS.

• The PFS of patients with PS 0 was better than that of patients with PS ≤ 1.

Figure 2. Objective response rates (ORRs) in each subgroup

A) Clinical subtype, B) Presence or absence of BRAF mutation, C) Dose of nivolumab, D) Performance status, and E) Treatment sequence.

Figure 3. Progression-free survival (PFS) in each subgroup

A) Clinical subtype, B) Presence or absence of BRAF mutation, C) Dose of nivolumab, D) Performance status, and E) Treatment sequence.

CONCLUSIONS

• The results of this interim analysis of the real-world use of nivolumab showed that the RR and PFS in Japanese patients were lower than those reported in the recent phase III randomized trials (RR, 40-44% in median PFS, 5.1 months) that included patients from 15 countries.

• The difference in the incidence of the clinical subtypes and treatment sequence between Japan and the western countries is associated with a low anti-tumor efficacy of nivolumab in Japan.

REFERENCES


ACKNOWLEDGEMENTS

This study was sponsored by the Public Health Research Foundation under the funding support from Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb K.K.