IMFINZI® Injection 120 mg, 500 mg

Specific-Clinical Experience Investigation in patients with locally advanced unresectable non-small cell lung cancer who are treated with maintenance therapy after definitive chemoradiation therapy.

1 Subject population

A total of 634 patients who had started IMFINZI treatment from October 2018 to July 2019 were registered, and 630 patients were included in the safety analysis.

2 IMFINZI administration

The mean treatment period of IMFINZI was 211.0 ± 138.6 days (Mean ± SD), the median was 222.5 days (ranging from 1 to 406 days), and 227 (36.0%) patients were given IMFINZI until 12 months which was the longest treatment period. IMFINZI treatment was discontinued in 398 patients (36.0%). The main reasons for discontinuation were "disease progression" in 174 (27.6%), "ILD/RP-related events" (interstitial lung disease including radiation pneumonitis) in 112 (17.8%), and "adverse events other than ILD/RP-related events" in 75 (11.9%).

3 Results

The incidence of ILD/RP-related events was 64.0% (403/630), including "radiation pneumonitis" in 57.6% (363/630 cases), "interstitial lung disease" in 8.6% (54/630), "pneumonitis" in 0.3% (2/630), and "radiation pulmonary fibrosis" in 0.2% (1/630).

The maximum severity (CTCAE Grade) of 403 patients with ILD/RP-related events was "Grade 1" in 172 (42.7%), "Grade 2"in 177 (43.9%), "Grade 3" in 41 (10.2%), “Grade 4” in 2 (0.5%), and “Grade 5" in 11 (2.7%). When the incidence of the events was viewed in a ratio to 630 included in the safety analysis, it was 27.3% for “Grade 1”, 28.1% for "Grade 2", 6.5% for "Grade 3", 0.3% for "Grade 4", and 1.7% for "Grade 5". The incidence of ILD/RP-related events in the Japanese population in the clinical study (PACIFIC study) was 73.6% in all Grades, 5.6% in Grades 3 and 4, and 1.4% in Grade 5, so the incidence of ILD/RP-related events and the maximum severity (CTCAE Grade) were generally consistent with the results of the PACIFIC trial.

In multivariate analysis using multivariate logistic regression model, dose distribution (V_{20}) of "25% or more" was the only explanatory factor possibly involved in the development of ILD/RP-related events of all Grades. When the events are limited to ILD/RP-related events of CTCAE Grade 2 or higher, it has been shown that ILD/RP-related events at baseline may also be a factor. Regarding ILD/RP-related events before durvalumab treatment, electronic package insert and appropriate use guide described the precautions, and it is necessary to continue to call attention using these materials.

4 Conclusion

Based on the above survey results, there was no new safety concern and no change in the benefit risk balance of IMFINZI.