LYMPARZA Tablets 100mg, 150mg
Clinical Experience Investigation
(All Patient Investigation)

1. Subject population

The study was initiated simultaneously with the launch of the Lynparza, and patients who started Lynparza treatment from April to July 2018 were enrolled. A total of 846 patients were enrolled and 842 CRFs were collected. Regarding the 842 patients with CRF collected, 838 patients were included in the safety analysis set, and 808 patients were included in the efficacy analysis set.

2. Lymparza administration

In the 838 patients in safety analysis set, the administration of Lymparza, including cessation periods was as follows.

Administration of Lymparza was continued for " ≤ 3 months" in 200 patients (23.9%), " 3 months to 6 months" in 148 patients (17.7%), "6 months to 9 months" in 123 patients (14.7%), "9 months to 12 months" in 243 patients (29.0%), and "> 12 months" in 124 patients (14.8%).

Lymparza was discontinued in 533 patients (63.6%). The most common reason for discontinuation was "Lack of efficacy" in 366 patients (68.7%), followed by "Adverse events development" in 122 patients (22.9%), "Others " in 27 patients (5.1%), and "Stopped visiting the hospital (transferred to other hospital, relocation, etc.)" in 18 patients (3.4%).

3. Safety

Of the 838 patients in safety analysis set, adverse drug reactions occurred in 663 cases (79.1%). The major adverse drug reactions were anaemia in 332 cases (39.6%), nausea in 286 cases (34.1%), and fatigue in 105 cases (12.5%), which were similar to the result of clinical study. Regarding Safety Specification, adverse reactions related to myelosuppression were observed in 415 cases (49.5%), interstitial lung disease in 12 cases (1.4%), and secondary malignant tumor in 10 cases (1.2%), and there was no need to inform patients with renal dysfunction beyond the current description in the package insert, and no new safety issues were observed.

4. Efficacy

Of the 808 patients in efficacy analysis set, the Objective Response Rate was 36.0%, the Disease Control Rate was 61.1%, and the number of patients with disease progression was 418 (51.7%). As a result, no new issue related to the efficacy of Lynparza was recognised.

5. Conclusion

Based on the above, there are no new findings that may affect the benefit-risk balance of Lynparza.