Based on results from ARIEL3, rucaparib is approved in the United States and European Union

Taken together, these findings suggest that the impact of

Wild type/LOH low; and

For TEAEs of interest, the incidence of grade ≥2 events in the rucaparib

For TEAEs of interest, the incidence of grade ≥2 events in the rucaparib

Patients were asked to complete the EQ-5D-3L, EuroQol’s 5 dimension, a novel questionnaire at each of 1, 3, each treatment cycle, and treatment discontinuation visit, and at the final study visit.

Patient-Centered Outcomes Analyses

CONCLUSIONS

The overall incidence of grade ≥3 TEAEs was 9.8% in the placebo group and 21.8% in the rucaparib group (ITT). The most common grade ≥3 TEAEs were nausea (11.2% vs 25.1%), vomiting (8.1% vs 14.2%), diarrhea (4.5% vs 6.7%), and fatigue (4.4% vs 1.6%) for the placebo and rucaparib groups, respectively.

Table 2. D-TWIST Analyses (Grade ≥3 TEAEs) by LOH Status in Patients with a BRCA Wild-Type Carcinoma

Table 3. T-WiST Analyses (Grade ≥3 TEAEs) by LOH Status in Patients with a BRCA Wild-Type Carcinoma

Table 4. T-WiST Analyses (Grade ≥2 TEAEs) by LOH Status in Patients with a BRCA Wild-Type Carcinoma

- For TWEs of interest, the incidence of grade ≥2 events in the rucaparib group was lower than or equal to the placebo group.

- For grade ≥3 TWEs, the incidence in the rucaparib group was lower than in the placebo group in the wild type/LOH high groups.

- The incidence in wild type/LOH indeterminate groups was similar for both rucaparib and placebo.

- The incidence in wild type/LOH low groups was higher in the rucaparib group than in the placebo group.

- In the ITT population and subgroup of patients with a BRCA mutation, mean PFS was 16.53 months for the placebo and 5.64 months for the rucaparib group.

- In the PFS analyses of interest, the incidence of grade ≥2 events in the rucaparib group was lower than in the placebo group.

- The incidence in wild type/LOH indeterminate groups was similar for both rucaparib and placebo.

- The incidence in wild type/LOH high groups was lower in the rucaparib group than in the placebo group.

- In the ITT population and subgroup of patients with a BRCA mutation, mean PFS was 16.53 months for the placebo and 5.64 months for the rucaparib group.

- In the PFS analyses of interest, the incidence of grade ≥2 events in the rucaparib group was lower than in the placebo group.

- The incidence in wild type/LOH indeterminate groups was similar for both rucaparib and placebo.

- The incidence in wild type/LOH high groups was lower in the rucaparib group than in the placebo group.