INTRODUCTION

Here we present updated data from TRITON2 using an enrolment cutoff of 1 October 2019. Patients with measurable disease at baseline: confirmed ORR per modified RECIST/PCWG3 by central assessment (n=128), 53.8% (95% CI: 45.8-61.4%; p<0.0001 vs placebo) with a median time to PSA progression of 12 weeks (range, 12–150 weeks). Median duration of modified RECIST/PCWG3 response was 6 months (range, 1.1–98.9 months). Patients with no measurable disease at baseline: confirmed ORR per modified RECIST/PCWG3 by central assessment (n=98), 41.8% (95% CI: 30.4-53.2%; p=0.0010 vs placebo) with a median time to PSA progression of 12 weeks (range, 12–48 weeks). Median duration of modified RECIST/PCWG3 response was 4 months (range, 1.1–48 months).

RESULTS

- **Patients with measurable disease at baseline:** confirmed ORR per modified RECIST/PCWG3 by central assessment (n=128), 53.8% (95% CI: 45.8-61.4%; p<0.0001 vs placebo) with a median time to PSA progression of 12 weeks (range, 12–150 weeks). Median duration of modified RECIST/PCWG3 response was 6 months (range, 1.1–98.9 months).
- **Patients with no measurable disease at baseline:** confirmed ORR per modified RECIST/PCWG3 by central assessment (n=98), 41.8% (95% CI: 30.4-53.2%; p=0.0010 vs placebo) with a median time to PSA progression of 12 weeks (range, 12–48 weeks). Median duration of modified RECIST/PCWG3 response was 4 months (range, 1.1–48 months).

CONCLUSIONS

The safety profile of rucaparib was consistent with prior reports from TRITON2 and those reported for PARP inhibitors in combination with platinum, including a manageable profile of mostly Grade 1 and 2 adverse events with few Grade 4 and 5 events. Of note, there were two Grade 4 neutropenas and two Grade 4 thrombocytopenias. Two Grade 5 adverse events were reported: one Grade 5 abnormal liver function test, and one Grade 5 myelosuppression. Treatment interruption and/or dose reduction due to TEAE related to rucaparib were rare, occurring in 15 patients (3.6%). The most common treatment-related adverse events were decreased appetite (8.8%), nausea (8.4%), vomiting (8.2%), diarhoea (7.5%), dyspepsia (6.9%), and headache (6.9%). Oedema peripheral was observed in 2.8% of patients. One patient each due to disease progression, intestinal perforation and fucoidiis were reported as treatment-related deaths. Eight patients (1.9%) experienced grade 3 non-haematologic TEAEs and 1 patient each experienced grade 4 non-haematologic TEAEs.

DISCLOSURE

AstraZeneca, GlaxoSmithKline, and Zenith Epigenetics.
Disclosures

Wassim Abida has served in a consulting or advisory role for Clovis Oncology, Janssen, MORE Health, and ORIC Pharmaceuticals; has received financial support for travel and/or accommodation from Clovis Oncology and GlaxoSmithKline; has received honoraria from Caret Healthcare; and his institution has received research funding from Clovis Oncology, AstraZeneca, GlaxoSmithKline, and Zenith Epigenetics.

Akash Patnaik has served in a consulting or advisory role for Exelixis, Janssen, and Jounce Therapeutics, received honoraria from Clovis Oncology, Merck, Prime Inc, and Roche, and received research funding from Clovis Oncology, Bristol-Myers Squibb, and GlaxoSmithKline.

Brieuc Sautois has served a consulting or advisory role for Clovis Oncology, Janssen, Astellas, and Sanofi; has received financial support for travel and/or accommodation from Janssen.

Jeremy Shapiro has served in a consulting or advisory role for Amgen, Astellas Pharma, Ipsen, Merck, and Roche and received financial support for travel from Amgen and Merck.

Nicholas J. Vogelzang has served in a consulting or advisory role for Astellas Pharma, AstraZeneca, Bayer, Caris, Janssen, Pfizer, and Sanofi Aventis; holds stock options from Caris; and serves as an editor for Up-To-Date.

Jingsong Zhang has served in a consulting or advisory role and/or on speakers bureaus for AstraZeneca and Sanofi and received research funding from Astellas Pharma, AstraZeneca, and Bayer.

Andrew D. Simmons, Darrin Despain, Melanie Dowson, and Tony Golsorkhi are employees of Clovis Oncology and may own stock or have stock options in that company.

Simon Chowdhury has served in a consulting or advisory role and/or on speakers bureaus for Clovis Oncology, Astellas Pharma, Janssen, Pfizer, and Sanofi; received honoraria from GlaxoSmithKline and Novartis; and received research funding from Clovis Oncology, Johnson & Johnson, and Sanofi.

All other authors have nothing to disclose.