INTRODUCTION
• A phase 1/2 study (Study 1) and phase 3 trial (Study 2) of rucaparib in patients with platinum-sensitive, platinum-resistant, high-grade serous ovarian cancer (HGOC) and/or peritoneal pelvic cancer (Part 1A, ARIEL3) of BRCA1/2 mutation (germline and/or somatic) and/or high-grade epithelial ovarian cancer (Part 1B, ARIEL2) of BRCA1/2 mutation and/or HR, high-grade serous, BRCA1/2-mutated ovarian cancer (Part 2A), high-grade serous, platinum-sensitive, platinum-resistant, and platinum-resistant ovarian cancer (Part 2B, ARIEL2) were conducted.
• Overall, 3,021 patients were treated with rucaparib.
• The adverse events observed in the integrated analysis, listed by preferred term and by treatment settings (Table 2).

METHODS
• Patients with HGOC with platinum-sensitive, platinum-resistant, or high-grade epithelial ovarian cancer (together, HGOC) with BRCA1/2-mutation or high-grade serous, platinum-sensitive or platinum-resistant ovarian cancer were included.
• Patients were treated in maintenance setting (Table 3).
• The full analysis set consists of all patients treated with study drug.

RESULTS
• A total of 573 patients from Study 1, ARIEL2, and ARIEL3 were included in these safety analyses (Table 1).

CONCLUSIONS
• The results of this integrated analysis of patients with ovarian cancer who received rucaparib in the treatment and maintenance settings are consistent with the known safety profile of rucaparib.

REFERENCES
• Cancer Res. 70, 2010

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DISCLOSURE
• The authors report no relevant financial relationships.

All unblinded, protocol, double-blind, phase 3 study to evaluate rucaparib as monotherapy or combination therapy in patients with advanced ovarian cancer (Cancer Res. 71, 2011)
• Key patient eligibility criteria for these studies are summarized in Table 1.

Figure 1. Key Patient Eligibility Criteria

Table 2. Summary of TEAEs

Table 3. Maintenance Setting

Figure 3. Median Time to First Occurrence of the Most Frequent Reported TEAEs

Figure 4. Median Time to First Occurrence of Any Grade TEAEs

Figure 5. Median Time to First Occurrence of Grade ≥3 TEAEs

Table 4. Summary of Any Grade TEAEs

Table 5. Summary of Grade ≥3 TEAEs

Table 6. Summary of Treatment-Related TEAEs

Table 7. Summary of TEAEs in Part 1B (ARIEL2)

Table 8. Summary of TEAEs in Part 1A (ARIEL3)
Disclosures

Rebecca S. Kristeleit has served on advisory boards for Clovis Oncology, Roche, and Tesaro.

Amit M. Oza has served on advisory boards for Clovis Oncology, Amgen, Immunovaccine, and Verastem; received support for travel or accommodation from AstraZeneca; and received honoraria from WebRx.

Ana Oaknin has served on advisory boards for Clovis Oncology, AstraZeneca, ImmunoGen, Genmab/Seattle Genetics, PharmaMar, Roche, and Tesaro and received support for travel or accommodation from AstraZeneca, PharmaMar, Roche, and Tesaro.

Carol Aghajanian has served on steering committees for Clovis Oncology and Mateon Therapeutics; served on advisory boards for Clovis Oncology, Bayer, Cerulean Pharma, Tesaro, and VentRx; and received honoraria from Clovis Oncology, Bayer, Cerulean Pharma, Mateon Therapeutics, Tesaro, and VentRx.

Anna V. Tinker has served on an advisory board for and received grants from AstraZeneca.

Carol Aghajanian has served on steering committees for Clovis Oncology and Mateon Therapeutics; served on advisory boards for Clovis Oncology, Bayer, Cerulean Pharma, Tesaro, and VentRx; and received honoraria from Clovis Oncology, Bayer, Cerulean Pharma, Mateon Therapeutics, Tesaro, and VentRx.

Carol Aghajanian has served on steering committees for Clovis Oncology and Mateon Therapeutics; served on advisory boards for Clovis Oncology, Bayer, Cerulean Pharma, Tesaro, and VentRx; and received honoraria from Clovis Oncology, Bayer, Cerulean Pharma, Mateon Therapeutics, Tesaro, and VentRx.

Anna V. Tinker has served on an advisory board for and received grants from AstraZeneca.

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David M. O'Malley has served on advisory boards for Clovis Oncology, AstraZeneca, Gynecologic Oncology Group, Janssen, Myriad, and Tesaro; has served on steering committees for Clovis Oncology, Amgen, and ImmunoGen; has served as a consultant to Abbvie, Amry, AstraZeneca, Health Analytics, and Tesaro; and his institution has received research support from Clovis Oncology, Agenus, Ajinomoto, Array BioPharma, AstraZeneca, Bristol-Myers Squibb, ERGOMED Clinical Research, Exelixis, Genentech, GlaxoSmithKline, Gynecologic Oncology Group, ImmunoGen, INC Research, inVentiv Health Clinical, Janssen Research and Development, Ludwig Institute for Cancer Research, Novartis Pharmaceuticals, PRA International, Regeneron Pharmaceuticals, Serono, Stemcentrx, Tesaro, and TRACON Pharmaceuticals.

Alexandra Leary has served on advisory boards for Clovis Oncology, Pfizer, and PharmaMar; reports institutional research grant support from GamaMabs and Merus; and reports boarding and travel expenses for congress activities from AstraZeneca.

Gottfried E. Konecny has served on speakers bureaus for Clovis Oncology and AstraZeneca; received research funding from Amgen and Merck; and received honorarium from Novartis.

Domenica Lorusso has served in a consulting or advisory role for Clovis Oncology, AstraZeneca, ImmunoGen, Merck, PharmaMar, Roche, Takeda, and Tesaro and received support for travel or accommodation from PharmaMar and Roche.

Johanne I. Weberpals has received research support from Abbvie and AstraZeneca and served on advisory boards for AstraZeneca.

Sandra Goble, Lara Maloney, and Terri Cameron are employees of Clovis Oncology and may own stock or have stock options in that company.

Elizabeth M. Swisher has nothing to disclose.

Iain A. McNeish has served on advisory boards for Clovis Oncology, AstraZeneca, Takeda, and Tesaro and receives institutional funding from AstraZeneca.

Ronnie Shapira-Frommer has served on advisory boards for Clovis Oncology and Merck/Merck Sharp & Dohme.

Jonathan A. Ledermann has received lecture fees from Clovis Oncology, AstraZeneca, and Pfizer; served on advisory boards for Clovis Oncology, Artios Pharma, AstraZeneca, Cristal Therapeutics, Merck/Merck Sharp & Dohme, Pfizer, Regeneron, Roche, Genentech, and Tesaro; and received research grants from AstraZeneca and Merck/Merck Sharp & Dohme.

Robert L. Coleman reports grants from Clovis Oncology, AbbVie, AstraZeneca, Esperance Janssen, Merck, Millennium, OncoMed, and Roche/Genentech and has served as an advisor to Clovis Oncology, AbbVie, AstraZeneca, Bayer, Esperance, GamaMabs, Genmab, Gradalis Janssen, Millennium, Merck, OncoMed, Pfizer, Roche/Genentech, and Tesaro.