

## IGCS meeting abstracts

## Plenary Sessions

## Plenary 1

## IGCS19-0523

1 **MILO/ENGOT-OV11: PHASE-3 STUDY OF BINIMETINIB VERSUS PHYSICIAN'S CHOICE CHEMOTHERAPY (PCC) IN RECURRENT OR PERSISTENT LOW-GRADE SEROUS CARCINOMAS OF THE OVARY, FALLOPIAN TUBE, OR PRIMARY PERITONEUM**

<sup>1</sup>R Grisham\*, <sup>2</sup>B Monk J, <sup>3</sup>S Banerjee, <sup>4</sup>R Coleman L, <sup>5</sup>A Oza M, <sup>6</sup>M Oehler K, <sup>7</sup>E Kalbacher, <sup>8</sup>M Mirza Raza, <sup>9</sup>J del Campo M, <sup>10</sup>C Marth, <sup>11</sup>A Westermann, <sup>12</sup>S Pignata, <sup>13</sup>N Colombo, <sup>14</sup>D Cibula, <sup>15</sup>F Hilpert, <sup>16</sup>C Aghajanian, <sup>17</sup>E Drill, <sup>18</sup>V Sandor, <sup>19</sup>A Boyd P, <sup>20</sup>I Vergote. <sup>1</sup>Memorial Sloan Kettering Cancer Center, Department of Medicine-Gynecologic Medical Oncology, New York, USA; <sup>2</sup>Arizona Oncology US Oncology Network-University of Arizona College of Medicine, Creighton University School of Medicine, Phoenix, USA; <sup>3</sup>Royal Marsden Hospital, Gynaecological Cancers at the Institute of Cancer Research, London, UK; <sup>4</sup>MD Anderson Cancer Center, Gynecologic Oncology and Reproductive Medicine, Houston, USA; <sup>5</sup>Princess Margaret Cancer Centre, Medical Oncology and Hematology, Toronto, Canada; <sup>6</sup>Royal Adelaide Hospital, Gynaecological Oncology, Adelaide- SA, Australia; <sup>7</sup>Centre Hospitalier Régional et Universitaire de Besançon, Oncology, de Besançon, France; <sup>8</sup>NSGO and Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark; <sup>9</sup>Vall d'Hebron University Hospital, Medical Oncology, Barcelona, Spain; <sup>10</sup>Innsbruck Medical University, Obstetrics and Gynecology, Innsbruck, Austria; <sup>11</sup>Amsterdam University Medical Centers, Dutch Gynaecological Oncology Group DGOG, Amsterdam, The Netherlands; <sup>12</sup>Istituto Nazionale Tumori Fondazione Pascale IRCCS, Medical Oncology, Naples, Italy; <sup>13</sup>Università Milano-Bicocca Direttore Programma Ginecologia Oncologica Istituto Europeo Oncologia, Dipartimento Medicina e Chirurgia, Milan, Italy; <sup>14</sup>First Faculty of Medicine- Charles University in Prague and General University Hospital in Prague, Obstetrics And Gynecology, Prague, Czech Republic; <sup>15</sup>Onkologisches Therapiezentrum am Krankenhaus, Gynecology, Jerusalem, Israel; <sup>16</sup>Array BioPharma Inc, Array, Boulder, USA; <sup>17</sup>Array BioPharma Inc, Biometrics and Clinical Operations, Boulder, USA; <sup>18</sup>Belgium and Luxemburg Gynaecological Oncology Group, Gynaecologic Oncology, Leuven, Belgium

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**Objectives** Low-grade serous ovarian carcinomas (LGSOC) have historically low chemotherapy responses. Alterations affecting the MAPK pathway, most commonly KRAS/BRAF, are present in 30–60% of LGSOC. A phase II study of the MEK inhibitor selumetinib showed promising response rate of 15% in LGSOC and binimetinib, a potent MEK1/2 inhibitor, has demonstrated activity across multiple cancers.

**Methods** MILO (MEK-Inhibitor in Low-grade Serous Ovarian Cancer)/ENGOT-ov11 was an open-label, 2:1-randomized study of binimetinib (45-mg BID) vs PCC in LGSOC. Eligible patients had recurrent or persistent measurable LGSOC following  $\geq 1$  prior platinum-based chemotherapy,  $\leq 3$  prior chemotherapy lines, and no prior MEK-or BRAF-inhibitor. The primary endpoint was progression-free survival (PFS) by blinded central review; additional assessments: overall survival (OS), overall response rate (ORR), duration of response (DOR), clinical-benefit rate, biomarkers, and safety. (NCT01849874).

**Results** 303 patients were randomized (201 binimetinib,102 PCC). Median PFS was 9.1 months (95% CI:7.3,11.3) for binimetinib and 10.6 months (95% CI:9.2,14.5) for PCC (HR:1.21(0.79,1.86);closed early for futility). Secondary efficacy endpoints were similar in the two groups: ORR 16%

(complete/partial responses[CR/PRs]=32) vs 13%(CR/PRs=13); median DOR 8.1 (range:0.3–12.0+ months) vs 6.7 (0.3–9.7+ months); and median OS 25.3 vs 20.8 months, for binimetinib and PCC, respectively. Safety results were consistent with known safety profile of binimetinib; most common  $\geq$ grade 3 events were blood CK increased(20%) and hypertension(20%). Post-hoc analysis suggests a possible association between KRAS mutation and response to binimetinib.

**Conclusions** Although MILO did not meet its primary endpoint, binimetinib showed activity in LGSOC across the efficacy endpoints evaluated. Chemotherapy responses were higher than predicted. Further evaluation is warranted.

## IGCS19-0455

2 **EXPLORATORY ANALYSIS OF POSTPROGRESSION AND PATIENT-CENTERED OUTCOMES IN ARIEL3: A PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED STUDY OF RUCAPARIB MAINTENANCE TREATMENT IN PATIENTS WITH RECURRENT OVARIAN CARCINOMA**

<sup>1</sup>R Coleman\*, <sup>2</sup>AM Oza, <sup>3</sup>D Lorusso, <sup>4</sup>C Aghajanian, <sup>5</sup>A Oaknin, <sup>6</sup>A Dean, <sup>7</sup>N Colombo, <sup>8</sup>JJ Weberpals, <sup>9</sup>AR Clamp, <sup>10</sup>G Scambia, <sup>11</sup>A Leary, <sup>12</sup>RW Holloway, <sup>13</sup>M Amenedo Gancedo, <sup>14</sup>PC Fong, <sup>15</sup>JC Goh, <sup>16</sup>DM O'Malley, <sup>17</sup>S Goble, <sup>18</sup>T Cameron, <sup>19</sup>J Bedel, <sup>20</sup>JA Ledermann. <sup>1</sup>The University of Texas MD Anderson Cancer Center, Department of Gynecologic Oncology and Reproductive Medicine, Houston- TX, USA; <sup>2</sup>Princess Margaret Cancer Centre- University Health Network, Division of Medical Oncology and Hematology, Toronto- ON, Canada; <sup>3</sup>Policlinico Universitario A. Gemelli IRCCS, Gynecologic Oncology Unit, Rome, Italy; <sup>4</sup>Memorial Sloan Kettering Cancer Center, Gynecologic Medical Oncology, New York- NY, USA; <sup>5</sup>Vall d'Hebron Institute of Oncology VHIO, Medical Oncology Department, Barcelona, Spain; <sup>6</sup>St John of God Subiaco Hospital, Department of Oncology, Subiaco- WA, Australia; <sup>7</sup>European Institute of Oncology and University of Milan-Bicocca, Gynecologic Cancer Program, Milan, Italy; <sup>8</sup>Ottawa Hospital Research Institute, Division of Gynecologic Oncology, Ottawa- ON, Canada; <sup>9</sup>The Christie NHS Foundation Trust and University of Manchester, Department of Medical Oncology, Manchester, UK; <sup>10</sup>Gustave Roussy Cancer Center- INSERM U981- and Groupe d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens GINECO, Gynecological Unit, Villejuif, France; <sup>11</sup>Florida Hospital Cancer Institute, Department of Gynecologic Oncology, Orlando- FL, USA; <sup>12</sup>Oncology Center of Galicia, Medical Oncology Department, La Coruña, Spain; <sup>13</sup>Auckland City Hospital, Medical Oncology Department, Grafton- Auckland, New Zealand; <sup>14</sup>Royal Brisbane and Women's Hospital and University of Queensland, Department of Oncology- Cancer Care Services, Herston and St Lucia- QLD, Australia; <sup>15</sup>The Ohio State University- James Cancer Center, Clinical Research Gynecologic Oncology, Columbus- OH, USA; <sup>16</sup>Clovis Oncology- Inc., Biostatistics, Boulder- CO, USA; <sup>17</sup>Clovis Oncology UK Ltd., Clinical Science, Cambridge, UK; <sup>18</sup>Clovis Oncology Switzerland GmbH, Pricing and Market Access – Europe, Zurich, Switzerland; <sup>19</sup>UCL Cancer Institute- University College London and UCL Hospitals, Department of Oncology, London, UK

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**Objectives** In ARIEL3, rucaparib maintenance treatment significantly improved progression-free survival (PFS) vs placebo. A prespecified exploratory analysis investigated postprogression outcomes. Additionally, a post hoc exploratory analysis investigated patient-centered outcomes during rucaparib maintenance treatment.

**Methods** Patients were randomized 2:1 to receive oral rucaparib (600 mg BID) or placebo. Postprogression endpoints included time to start of first subsequent therapy (TFST), time to second investigator-assessed PFS or death (PFS2), and time to start of second subsequent therapy (TSST); overall survival data are not yet mature. Patient-centered outcomes included quality-adjusted