Introduction The addition of hyperthermic intraperitoneal chemotherapy (HIPEC) during interval cytoreductive surgery increases progression-free and overall survival for patients with advanced-stage epithelial ovarian cancer in two randomized controlled trials (OV-HIPEC-01 and KOV-HIPEC-01). The aim of this trial is to identify the survival benefit of HIPEC in advanced ovarian cancer in the era of maintenance therapy of bevacizumab and/or PARP inhibitor.

Methods The KOV-HIPEC-04 is a multicenter, 1:1 randomized, phase III trial that will enroll 520 patients with primary epithelial ovarian cancer who completed neoadjuvant chemotherapy. Patients will be randomized at the time of interval cytoreductive surgery with achieving complete cytoreduction or cytoreduction with no more than 2.5 mm depth of residual disease to receive HIPEC (experimental arm, 41.0–42.0°C cisplatin 75 mg/m², 90 minutes) or not (control arm). After recovery from surgery, patients will receive postoperative platinum-based adjuvant chemotherapy followed by maintenance therapy with PARP inhibitor or bevacizumab. The primary endpoint is to evaluate overall survival (OS); secondary objectives are progression-free survival (PFS), cancer-specific survival, time to first subsequent therapy, safety, and quality of life. Assuming that the enrollment period is 5 years and the follow-up period is 3 years, the total number of events required is 263. Based on the log-rank test, the total number of subjects required to prove HR 0.67 with a two-sided alpha of 0.05 and 90% power is 494. 520 patients are finally studied, considering 5% drop-out. ClinicalTrials.gov (NCT05827523)

Current Trial Status Not yet Recruiting

Abstract TP018/#822 Figure 1

A RANDOMIZED, MULTICENTER, OPEN-LABEL PHASE III TRIAL OF HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER


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Introduction Recent randomized trials (OV-HIPEC-01 and KOV-HIPEC-01) and meta-analyses reveal survival benefits of
HIPEC after recent exposure of systemic chemotherapy exposure in ovarian cancer.

Methods This trial (KOY-HIPEC-02) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients in platinum-resistant recurrent epithelial ovarian cancer. The trial is registered on ClinicalTrials.gov (NCT05316181). The experimental arm will receive HIPEC (41.0–42.0°C, doxorubicin 35 mg/m² and mitomycin 15 mg/m², 90 min) followed by physician’s choice chemotherapy, and the control arm will receive physician’s choice chemotherapy without HIPEC until disease progression or unacceptable toxicities. The primary objective of the trial is to evaluate progression-free survival (PFS). Secondary objectives are overall survival (OS), cancer-specific survival, safety, and quality of life. Assuming that the enrollment period is 3 years and the follow-up period is 2 years, the total number of events required is 121. Based on the log-rank test, the total number of subjects required to prove HR 0.6 with a two-sided alpha 0.05 and 80% power is 126. 140 patients are finally studied considering 10% drop-out.

Current Trial Status Active Recruiting

TP019/#1387

ROSELLA (GOG-3073, ENGOT-OV72/MITO): A FIRST-IN-HUMAN PHASE 1/2 STUDY OF nab-Paclitaxel + nab-Paclitaxel in PLATINUM-RESISTANT OVARIAN CANCER

1Domenica Lorusso, 1Andrew Bagami, 1Erin Bishop, 1Anita Chudzeka-Clark, 2Alix Devaux, 3Laurence Gladieff, 4Mary Gordinier, 5Jae-Weon Kim, 6Jacob Korach, 7Michael Mccollum, 8Linda Mileshkin, 9Bradyly Monk, 10Sibani Nium, 11Angelica Nogueira-Rodrigues, 12Ana Oalini, 13David O’Malley, 14Mauro Orlando, 15Lyndah Drelling, 16Ilula Cristina Tudor, 17Alexander Olawaiye, 18Fondazione Policlinico Gemelli and Catholic University of the Sacred Heart, Division of Gynecologic Oncology, Rome, Italy; 19National Institute of Oncology, Gynecologic Oncology Research Center, Budapest, Hungary; 20Medical College of Wisconsin, Cancer Center, Milwaukee, USA; 21Pomeranian Medical University, Gynecological Surgery and Gynecological Oncology of Adults and Adolescents, Szczecin, Poland; 22Grand Hospital de Charleroi, Oncology, Charleroi, Belgium; 23Institut Claudius Regaud — IUCT-O, Oncology, TOULOUSE, France; 24Norton Healthcare, Norton Cancer Institute, Louisville, USA; 25Seoul National University, Obstetrics and Gynecology, Seoul, Korea; 26Republic of, 27Scheba Medical Center, Gynecologic Oncology, Ramat Gan, Tel Aviv, Israel; 28Virginia Oncology Associates, Brock Cancer Center, Norfolk, USA; 29Peter MacCallum Cancer Centre, Department of Medical Oncology, Melbourne, Australia; 30GOG-Foundation and HonorHealth University of Arizona College of Medicine and Creighton University School of Medicine, Division of Gynecologic Oncology, Phoenix, USA; 31University College London, Cancer Institute, London, UK; 32Federal University of Minas Gerais, Department of Obstetrics and Gynecology, Brazil; 33Belo Horizonte, Brazil; 34Val de l’Hébouvre Hospital, Oncology, Barcelonina, Spain; 35The Ohio State University and the James Cancer Center, Department of Obstetrics and Gynecology, Columbus, USA; 36Instituto Alexander Fleming, Pharmacology, Buenos Aires, Argentina; 37Concept Therapeutics, Inc., Research and Development, Menlo Park, USA; 38Concept Therapeutics, Inc., Biometrics, Menlo Park, USA; 39University of Pittsburgh, Obstetrics, Gynecology and Reproductive Sciences, Pittsburgh, USA

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Abstracts

Introduction Single-agent chemotherapies are commonly used in platinum-resistant ovarian cancer (OC), but outcomes are generally poor. Cortisol, which binds to the glucocorticoid receptor (GR), can suppress apoptotic pathways used by chemotherapy. The selective GR modulator relacorilant may reverse cortisol’s anti-apoptotic effects to enhance chemotherapy efficacy. In a phase 2 study in patients with recurrent, platinum-refractory/resistant OC (NCT03776812), intermittently dosed relacorilant + nab-paclitaxel showed clinically meaningful improvement in progression-free survival (PFS), duration of response (DoR), and overall survival (OS) without increased side effect burden vs. nab-paclitaxel monotherapy.

The ROSELLA study aims to confirm these findings in a larger patient population.

Methods ROSELLA (NCT05257408) is a randomized, phase 3, 2-arm, open-label study of relacorilant + nab-paclitaxel vs. nab-paclitaxel monotherapy. Approximately 360 women with platinum-resistant ovarian, primary peritoneal, or fallopian tube cancer who have received 1–3 prior systemic anticancer therapies, including prior bevacizumab, and ≥1 platinum-based therapy are being enrolled. Patients with primary platinum-refractory disease are excluded. Patients are being randomized 1:1 to relacorilant (150 mg the day before, of, and after nab-paclitaxel) + nab-paclitaxel (80 mg/m²) or nab-paclitaxel monotherapy (100 mg/m²); stratified by prior lines of therapy (1 vs >1) and region of world (North America vs. Europe vs. rest of world). Nab-paclitaxel is administered on days 1, 8, and 15 of each 28-day cycle. The primary endpoint is PFS by blinded independent central review. Key secondary and exploratory endpoints include OS, PFS by investigator assessment, objective response rate, best overall response, DoR, safety, pharmacokinetics, pharmacodynamics, patient-reported outcomes, and quality of life.

Current Trial Status Currently enrolling

TP020/#1513

FIRST-IN-HUMAN PHASE 1/2 STUDY OF UBAMATAMAB, A MUC16xCD3 BISPECIFIC ANTIBODY, ADMINISTERED ALONE OR IN COMBINATION WITH CEMIPLIMAB IN PATIENTS WITH RECURENT OVARIAN CANCER

1Kathleen Moore, 2Sara Bouberman, 3Erika Hamilton, 4Joyce Liu, 5Roisin O’Carroll, 6David O’Malley, 7Konstantinos Papamitrou, 8David Schröder, 9Els Van Nieuwenhuyzen, 10Suk-Young Yoo, 11Bin Wang, 12Mary Pettersan, 13Friscia Goncalves, 14Tamara Schmidt, 15Min Zhu, 16Israel Levy, 17Thomas Ulldriz, 18Elizabeth Miller, 19University of Oklahoma Health Sciences Center/Sarah Cannon Research Institute, Stephenson Cancer Center, Oklahoma City, OK, USA; 20Massachusetts General Hospital, Gynecologic Oncology Program, Boston, USA; 21Sarah Cannon Research Institute, Tennessee Oncology, Breast and Gynecologic Cancer Research, Nashville, USA; 22Dana-Farber Cancer Institute, Division of Gynecologic Oncology, Boston, USA; 23Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, Gynecologic Medical Oncology Service, New York, USA; 24The Ohio State University and the James Cancer Center, Division of Gynecologic Oncology In Obstetrics and Gynecology, Columbus, USA; 25Antwerp University Hospital, Department of Medical Oncology, Antwerp, Belgium; 26Grand Hospital de Charleroi, Service d’Oncologie-Hematologie, Charleroi, Belgium; 27Leuven Cancer Institute, Gynecology and Obstetrics, Leuven, Belgium; 28Regeneron Pharmaceuticals, Inc., Biostatistics, Tarrytown, USA; 29Regeneron Pharmaceuticals, Inc., Oncology Clinical Development, Tarrytown, USA; 30Regeneron Pharmaceuticals, Inc., Clinical Pharmacology, Tarrytown, USA

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