HIPEC after recent exposure of systemic chemotherapy exposure in ovarian cancer.

Methods This trial (KOV-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 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 PHASE 3 STUDY OF RELACORILANT + NAB-PACLITAXEL VS. NAB-PACLITAXEL IN PLATINUM-RESISTANT OVARIAN CANCER

1Domenica Iorosso, 2Andrea Bagamery, 3Erin Bishop, 4Anita Chudzeka-Plaza, 5Alex Devaux, 6Laurence Gladieff, 7Mary Gordijn, 8Jae-Heon Kim, 9Jacob Korach, 10Michael Mccollum, 11Linda Mileshkin, 12Bradley Monk, 13Sibhani Nium, 14Angélica Nogueira-Rodríguez, 15Ana Oarkin, 16David O’Malley, 17Mauro Orlando, 18Lyndah Drelling, 19Iulia Cristina Tudor, 20Alexander Olawaiye, 21Fondazione Policlinico Gemelli and Catholic University of the Sacred Heart, Division of Gynecologic Oncology, Rome, Italy; 22National Institute of Oncology, Gynecologic Oncology Program, Budapest, Hungary; 23Medical College of Wisconsin, Cancer Center, Milwaukee, USA; 24Pomeranian Medical University, Medical Surgery and Gynecology Oncology of Adults and Adolescents, Szczecin, Poland; 25Grand Hospital de Charleroi, Oncology, Charleroi, Belgium; 26Institut Claudius Regaud – IUCT-O, Oncology, TOULOUSE, France; 27Norton Healthcare, Norton Cancer Institute, Louisville, USA; 28Seoul National University, Obstetrics and Gynecology, Seoul, Korea; 29Republic of; 30Sheba Medical Center, Gynecology Oncology, Ramat Gan, Tel Aviv, Israel; 31Virginia Oncology Associates, Brock Cancer Center, Norfolk, USA; 32Peter MacCallum Cancer Centre, Department of Medical Oncology, Melbourne, Australia; 33GOG-Foundation and HoneorHealth University of Arizona College of Medicine and Creighton University School of Medicine, Division of Gynecologic Oncology, Phoenix, USA; 34University College London, Cancer Institute, London, UK; 35University of Minas Gerais, Divom Oncology and Oncocrinics – Brazil; 36Belo Horizonte, Brazil; 37Val de Hebron University Hospital, Oncology, Barcelona, Spain; 38The Ohio State University and the James Cancer Center, Department of Obstetrics and Gynecology, Columbus, USA; 39Institute Alexander Fleming, Oncology, Buenos Aires, Argentina; 40Concept Therapeutics, Inc., Research and Development, Menlo Park, USA; 41Concept Therapeutics, Inc., Biometrics, Menlo Park, USA; 42University of Pittsburgh, Obstetrics, Gynecology and Reproductive Sciences, Pittsburgh, USA

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Introduction Ubamatamab (REGN4018) is a MUC16xCD3 bispecific antibody that promotes T cell-mediated cytotoxicity by facilitating contact between cancer cells and T cells. In a Phase 1 study (NCT03564340) in patients with recurrent ovarian cancer (OC), ubamatamab monotherapy demonstrated an acceptable safety profile and durable clinical activity at doses of 20 mg to 800 mg IV weekly (by RECIST and CA-125 response rates), and linear pharmacokinetics up to 800 mg IV weekly.

Methods In Phase 2, up to 150 patients with advanced platinum-resistant OC and elevated serum CA-125 will be randomized 1:1:1 to IV Q3W treatment: ubamatamab 250 mg; or ubamatamab 800 mg; or ubamatamab 250 mg plus cemiplimab 350 mg (figure 1). All treatment arms will include weekly step-up dosing of ubamatamab (1 mg week 1, 2 mg week 2, and full dose weeks 3 and 4) to limit risk of...
Abstract TP020/#1513 Figure 1 (A) Phase 1 dose escalation and Phase 2 dose expansion including randomized Phase 2 cohort and (B) study schema for randomized Phase 2 cohort.

Introduction Folate receptor alpha (FolRα) is a validated target in the treatment of platinum resistant ovarian cancer (PROC) expressing high-FolRα. There remains a high unmet need to treat PROC with low to moderate FolRα expression. Luveltamab tazevibulin (luvelta), a novel FolRα-targeting ADC with a hemiasterlin warhead (DAR4), is designed using site-specific conjugation technology to target a broad range of FolRα-expressing cancers. Luvelt a demonstrated preliminary efficacy data (ORR of 37.5%; mDOR of 5.5 months; mPFS of 6.1 months) in 32 patients with advanced/relapsed EOC with FolRα expression of >25% (any intensity) in a Ph1 study (NCT03748186). ORR was higher at 5.2 mg/kg (43.8% versus 31.3%, n=32) compared to 4.3 mg/kg. Luvelta showed a manageable safety profile, with the most common grade 3+ adverse events of neutropenia, arthralgia, and anemia. This data forms the basis for a pivotal study of luvelta in patients with PROC with broad FolRα expression levels.

Methods REFRaME-O1/ENGOT-Ov79/GOG-3086 is a 2-part Phase 2/3 study of luvelta in subjects with relapsed PROC expressing FolRα. Part 1 is the dose-optimization stage, with ~50 subjects randomized 1:1 at 4.3 mg/kg Q3W or 5.2 mg/kg Q3W + prophylactic pegfilgrastim for 2 cycles followed by 4.3 mg/kg Q3W. Part 2 will commence with the selected optimized dose versus investigator’s choice chemotherapy, with a 2:1 randomization schedule. Key inclusion criteria: progressive PROC, up to 3 prior regimens, TPS of ≥25% for FolRα expression, and measurable disease. Key exclusion criteria: primary platinum refractory disease and prior treatment with a FolRα ADC or ADC-containing tubulin inhibitor.

Current Trial Status Currently enrolling

1R Wendel Naumann*, 2Antonio González-Martin, 3Thomas Herzog, 4Robert Coleman, Isabelle Ray-Coquard, 6Rowan Miller, 7Lin Lu, 8Hatem Dokainish, 9Craig Berman, 10Ana Oaknin. 1Levine Cancer Institute, Carolinas Medical Center, Gynecologic Oncology, Charlotte, USA; 2Clinical Universidad de Navarra, Medical Oncology, Madrid, Spain; 3University of Cincinnati Cancer Center, Obstetrics and Gynecology, Cincinnati, USA; 4US Oncology Research, Gynecologic Oncology, The Woodlands, USA; 5CENTRE LEON BERARD, Oncology, LYON, France; 6University College London, St Bartholomew’s Hospitals, Gynaecological Oncology, London, UK; 7Sutro Biopharma, Biometrics, SSF, USA; 8Sutro Biopharma, Clinical Science, SSF, USA; 9Sutro Biopharma, Clinical Development, SSF, USA; 10Vall d’Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d’Hebron, Vall d’Hebron Barcelona Hospital Campus, Gynaecologic Cancer Programme, Barcelona, Spain

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