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Clinical Trial Protocol

Phase II randomized study of dostarlimab alone or with bevacizumab versus non-platinum chemotherapy in recurrent gynecological clear cell carcinoma (DOVE/APGOT-OV7/ENGOT-ov80)

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ABSTRACT

Background: Recurrent gynecological clear cell carcinoma (rGCCC) has a low objective response rate (ORR) to chemotherapy. Previous preclinical and clinical data suggest a potential synergy between immune checkpoint inhibitors and bevacizumab in rGCCC. Dostarlimab, a humanized monoclonal antibody targeting programmed cell death protein 1 (PD-1), combined with the anti-angiogenic bevacizumab, presents a novel therapeutic approach. This study will investigate the efficacy of dostarlimab +/– bevacizumab in rGCCC.
Methods: DOVE is a global, multicenter, international, open-label, randomized phase 2 study of dostarlimab +/– bevacizumab with standard chemotherapy in rGCCC. We will enroll 198 patients with rGCCC and assign them to one of three groups in a 1:1:1 ratio: arm A (dostarlimab monotherapy), B (dostarlimab + bevacizumab), and C (investigator's choice of chemotherapy [weekly paclitaxel, pegylated liposomal doxorubicin, doxorubicin, or gemcitabine]). Patients with disease progression in arm A or C will be allowed to cross over to arm B. Stratification factors include prior bevacizumab use, prior lines of therapy (1 vs. >1), and primary site (ovarian vs. non-ovarian). Key inclusion criteria are histologically proven

Presentation
This study was presented at the Annual Meeting of American Society of Clinical Oncology, Chicago, Illinois, 2024.

Conflict of Interest
Dr. KYT reports receiving research funding from AstraZeneca. Further, Dr. Tse also reports receiving payments or honoraria from AstraZeneca, Zai Lab, MSD, GlaxoSmithKline, and Eisai for lectures, presentations, speakers bureaus, manuscript writing, or educational events; and receiving support for attending meetings and/or travel from Zai Lab. She reports participation on a Data Safety Monitoring Board or Advisory Board for AstraZeneca, Eisai, MSD, and GlaxoSmithKline.

Dr. Clare Scott reports receiving research funding from AstraZeneca, Boehringer Ingelheim, Eisai Inc., Sierra Oncology, and Ideaya, royalties from WEHI Abbott Venetoclax (institutional), and support for attending meetings from MSD national and international and AstraZeneca national and participating on a Data Safety Monitoring Board or serving on advisory boards for AstraZeneca, Eisai, Sierra Oncology, Takeda, GSK, MSD, and OncologyOne. She also reports participation in the ANZGOG board (Australia and New Zealand Gynaecological Oncology Group) and International Rare Cancer Initiative as a Chair, and the Gynaecological Cancer InterGroup, BioGrid Australia, and Cancer Trials Australia as a Director. Dr. Scott further declares receipt of a drug from Beigene, and manuscript writing support from AstraZeneca.

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recurrent or persistent clear cell carcinoma of the ovary, endometrium, cervix, vagina, or vulva; up to five prior lines of therapy; disease progression within 12 months after platinum-based chemotherapy; and measurable disease. Key exclusion criteria are prior treatment with an anti–PD-1, anti–programmed death-ligand 1, or anti–programmed death-ligand 2 agent. The primary endpoint is progression-free survival determined by investigators. Secondary endpoints are ORR, disease control rate, clinical benefit rate, progression-free survival 2, overall survival, and toxicity. Exploratory objectives include immune biomarkers.

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Keywords: Carcinoma; Gynecology; Immunotherapy

INTRODUCTION

Gynecological clear cell carcinoma (GCCC) is a rare histological subtype of gynecological cancer, with a higher incidence in Asian than in Western countries. For instance, ovarian clear cell carcinoma (OCCC) constitutes 10.3%, 18.6%, and 25% of all epithelial ovarian cancers in Korea, Taiwan, and Japan, respectively, while in the US, it accounts for 4.8% cases among Caucasians and 11.1% among Asians [1].

GCCC, including OCCC, endometrial clear cell carcinoma, and cervical clear cell carcinoma, generally exhibits poor response rates to conventional chemotherapy [2,3]. A Korean multicenter study reported poor outcomes in advanced-stage clear cell carcinoma treated with neoadjuvant chemotherapy followed by interval debulking surgery, with a median progression-free survival (PFS) of 9.6 months and a median overall survival (OS) of 35.7 months [4]. Similarly, recurrent GCCC has shown low objective response rates (ORRs) to chemotherapy, with median PFS and ORRs being particularly disappointing [2,3]. In the NiCCC study, chemotherapy demonstrated a 0% ORR and a median PFS of 1.9 months in OCCC. In the KN775 study, a subgroup analysis showed a 0% ORR and a median PFS of 2 months in endometrial clear cell carcinoma.

Previous studies have suggested a potential synergy between immune checkpoint inhibitors and angiogenic agents like bevacizumab in recurrent gynecological clear cell carcinoma (rGCCC). MMR deficiency; increased expression of programmed cell death protein 1 (PD-1), TIM3, and LAG3; and upregulation of HNF-1β in OCCC often lead to an immune-suppressive tumor microenvironment, underscoring the need for clinical trials investigating immune checkpoint inhibitors [3].

Although some trials have shown promising results with immune checkpoint inhibitors in GCCC, the efficacy remains variable. For example, the KEYNOTE-100 study demonstrated an ORR of 15.8% in OCCC patients treated with pembrolizumab [5]. Hamanishi et al. [6] reported that 2 of 20 patients with platinum-resistant epithelial ovarian cancer experienced a complete response in a phase II trial of nivolumab.

Several trials have specifically focused on GCCC treatment. The PEACOCC study showed an ORR of 25% with pembrolizumab monotherapy in rGCCC [7]. Moreover, Moreover, the combination of anti-angiogenic and immune checkpoint blockade therapies has shown promising results, with some studies reporting an ORR of approximately 40% [8,9], but not

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in others, such as the MOCCA/APGOT-OV2 trial, which did not show improved outcomes with anti–programmed death-ligand 1 (PD-L1) compared with standard chemotherapy [10]. Therefore, no approved immunotherapy for GCCC exists, highlighting a critical unmet need in clinical practice.

MATERIALS AND METHODS

1. Objectives

The DOVE study is a three-arm randomized phase II trial designed to evaluate the efficacy of dostarlimab alone or in combination with bevacizumab versus non-platinum chemotherapy in rGCCC. This study aims to address the urgent need for more effective treatments for rGCCC and to explore the potential of switching from chemotherapy to immune therapies, potentially establishing a new standard of care.

2. Trial design

DOVE is a global, multicenter, international, open-label, randomized phase 2 study evaluating dostarlimab +/– bevacizumab with standard chemotherapy in rGCCC. The study involves sites from APGOT (Korea, Japan, Singapore, Australia, New Zealand, and Hong Kong), ENGOT (UK, France, Spain, and Belgium), and Canada. Institutional review board approval will be obtained from each site. Enrolled patients will be randomized in a 1:1:1 ratio to receive dostarlimab alone (arm A), dostarlimab plus bevacizumab (arm B), or the investigator's choice of chemotherapy (arm C: weekly paclitaxel, pegylated liposomal doxorubicin, doxorubicin, gemcitabine) until disease progression, intolerable toxicity, or withdrawal of patient consent for up to 24 months (**Fig. 1**). Patients in arm A or C with disease progression will be allowed to cross over to arm B after discussion with the coordinating investigator.

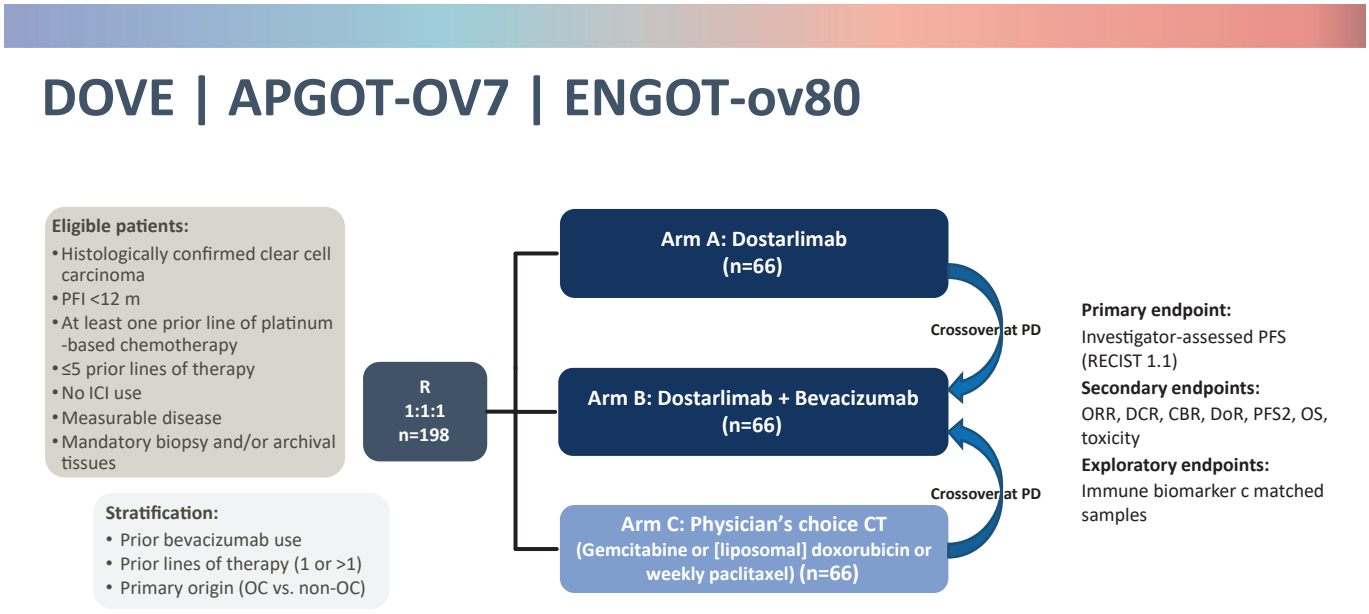

Fig. 1. Trial design.
CBR, clinical benefit rate; DCR, disease control rate; DoR, duration of response; ICI, immune checkpoint inhibitor; OC, ovarian cancer; ORR, objective response rate; OS, overall survival; PFI, platinum-free interval; PFS, progression-free survival.

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Dr. SL reports receiving research grants from AstraZeneca, GSK, Repare Therapeutics, and Roche (to the institution); additional institutional funding as a local principal investigator from Roche, GSK, Repare Therapeutics, Merck, AstraZeneca; research funding from Cancer Science Institute, Singapore, and National University of Singapore. She also reports receiving

Each treatment cycle will last for 3 weeks for arms A and B, with dose reductions allowed for treatment-related toxicities in arm C. Tumor measurements will be performed every 6 weeks for the first 6 months, every 9 weeks for the first 1 year, and every 12 weeks for up to 2 years post-treatment. Tumor response will be assessed using Response Evaluation Criteria in Solid Tumors (RECIST 1.1).

3. Participants

Key inclusion criteria are histologically proven recurrent or persistent clear cell carcinoma of the ovary, endometrium, cervix, vagina, or vulva; up to five prior lines of therapy; disease progression within 12 months after platinum-based chemotherapy; and measurable disease. Tumors with mixed histology will be eligible if > 50% consists of clear cell carcinoma. For ovarian tumors, WT1 negativity will be required. Archival tissue of sufficient quality must be procured or a mandatory pretreatment biopsy must be performed in each case. Key exclusion criteria are prior treatment with an anti–PD-1, anti–PD-L1, or anti–PD-L2 agent.

4. Endpoints

The primary endpoint is PFS by investigator assessment, defined as the time from randomization to the first documentation of disease progression or death from any cause. Secondary endpoints include ORR, disease control rate, clinical benefit rate, duration of response (DoR), PFS2, OS, and toxicity.

Exploratory endpoints aim to identify novel predictive biomarkers of response and resistance to dostarlimab +/-bevacizumab such as MMR status; tumor mutation burden (TMB); immune signature; and mutational profiles like PTEN loss, PIK3CA, and ARID1A mutations. The efficacy endpoints will be analyzed by comparing arms A and B with arm C (A vs. C and B vs. C). Adjustment of the type I error for multiplicity will not be considered. Radiological disease progression will be evaluated using RECIST 1.1 in arm C and RECIST 1.1 and iRECIST in arms A and B.

5. Sample size

Patients will be randomized 1:1:1 to receive dostarlimab, dostarlimab plus bevacizumab, or chemotherapy. The sample size calculation assumes a median PFS of 2 months in the standard chemotherapy arm and a hazard ratio of 0.67, translating to a median PFS of 3 months in the dostarlimab +/– bevacizumab arms. The study plans for a type I error of 10% (one-sided), type II error of 20% (80% power), with a 2-year accrual period, a minimum 1-year follow-up, and one interim analysis. A total of 175 events and 177 patients (59 per arm) will be needed, adjusting for a 10% dropout rate, leading to the enrollment of 198 patients.

6. Randomization

Randomization will be performed within 1 week prior to C1D1. Eligibility will be confirmed before randomization using stratified block randomization with stratification factors including prior bevacizumab use (yes or no), prior lines of therapy (1 vs. >1), and primary tumor site (ovarian vs. non-ovarian). Patients will be randomized via the Interactive Web Response System.

7. Statistical methods

Efficacy analysis will be conducted primarily in the ITT and PP populations, with ITT as the primary analysis set. All statistical analyses, except for the primary efficacy endpoint, will use a two-sided test at a 5% significance level. Efficacy endpoints will be analyzed by comparing

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Author Contributions

Conceptualization: J.Y.L.; Data curation: J.Y.L., E.Y.Y., K.W.; Formal analysis: J.Y.L., J.B.L., R.Y.H.; Funding acquisition: L.J.Y.; Investigation: E.Y.Y., K.W.; Methodology: J.B.L.; Project administration: L.J.Y., D.T., I.R., B.G.K., E.V.N., K.Y.T., A.G., C.S., K.H., S.L., R.K.; Resources: J.Y.L., R.K.; Software: J.B.L. R.Y.H.; Supervision: L.J.Y., D.T., I.R., B.G.K., E.V.N., K.Y.T., A.G., C.S., K.H., S.L., R.K.; Validation: J.B.L., R.Y.H., E.Y.Y., K.W.; Visualization: E.Y.Y., K.W., J.B.L., R.Y.H.; Writing - original draft: J.Y.L.; Writing - review & editing: J.Y.L, D.T., I.R., B.G.K., E.V.N., K.Y.T., A.G., C.S., K.H., S.L., R.K.

arms A and B with arm C (A vs. C and B vs. C). Adjustment of the type I error for multiplicity will not be considered. The primary efficacy endpoint will be analyzed at a minimum follow-up period of 1 year or after 175 PFS events. It will be determined based on the investigator's assessment and analyzed according to the treatment group and strata assigned at screening. PFS will be estimated using the Kaplan–Meier method. The median PFS and 95% confidence intervals will be presented per the treatment group, and the stratified log-rank test will be used for comparison between treatment groups. DoR, OS, PFS2, time to first subsequent treatment, and time to second subsequent treatment will be estimated using the Kaplan–Meier method, and the median duration will be presented along with a 95% confidence interval. A log-rank test will be used for comparisons between treatments.

8. Planned interim analyses

Interim efficacy analysis is planned for futility assessment. Cutoff values for the interim analyses will be based on investigator-assessed PFS events. Summaries and analyses will be prepared using DSMB to retain blinding. An interim analysis will be performed after 87 PFS events (approximately 50% of the total PFS events). The primary efficacy endpoint (PFS) will be calculated for each group. The following early termination criterion is planned based on the time of completion of the 87 PFS events: if the interim analysis time is changed according to the discussion between the DSMB and sponsor, the early termination criterion can be changed by revising them to the corresponding boundary value.

9. Trial registration ID

The study was registered at Clinicaltrials.gov (NCT06023862).

DISCUSSION

To our knowledge, DOVE/APGOT-OV7/ENGOT-ov80 is the largest ongoing study to explore the efficacy and safety of immunotherapy in rGCCC. Previous studies on single immunotherapies for rGCCC have shown varying results among different ethnic groups, highlighting the need for more inclusive and extensive investigations.

Non-ovarian GCCC is an uncommon and poorly understood entity. This study provides a unique opportunity to explore the characteristics of clear cell carcinoma in the endometrium, cervix, vagina, and vulva. Ovarian and endometrial clear cell carcinomas share similar molecular profiles, including HNF-1β overexpression, high rates of ARID1A mutations, and an immune-suppressive tumor microenvironment [11]. It is valuable to conduct a subgroup analysis based on primary sites, and we have capped the enrollment of non-ovarian cases at 10% of the total study population.

This international, multicenter study included participants from a diverse range of countries across Europe, North America, and Asia, such as Korea, Japan (GOTIC), Singapore (GCGS), Australia, New Zealand (ANZGOG), Hong Kong, the UK (GTG-UK), France (GINECO), Spain (GEICO), Belgium (BGOG), and Canada (PMHC). The inclusion of these varied geographic regions ensures a broad patient population encompassing different ethnicities, enhancing the trial's robustness and applicability across diverse demographic groups.

A notable feature of the DOVE trial is its innovative design, which allows for crossover to combination therapy with dostarlimab and bevacizumab upon disease progression.

This flexibility ensures that patients have access to potentially more effective treatments as their disease evolves. Another key strength of the DOVE trial is its comprehensive biomarker analysis plan, which utilizes both tumor and blood samples to assess a wide array of biomarkers. This includes well-established markers such as MMR status, TMB, immune signatures, and specific mutations such as PTEN loss and PIK3CA. The trial also incorporates high-dimensional analyses to identify novel biomarkers that could predict responses to therapy and provide insights into resistance mechanisms.

The trial's robust sample collection and analysis protocol will facilitate a deeper understanding of the tumor microenvironment and its interactions with the immune system. Previous studies have often been limited by small sample sizes, which have hindered the ability to conduct such in-depth translational research. The extensive biomarker analyses planned for the DOVE trial have the potential to overcome these limitations and provide valuable insights into predictors of response in rGCCC, thereby guiding future treatment strategies.

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