

the first-line maintenance setting via Early Access Programmes (Italy, UK), Temporary Use Authorization (France) or reimbursement following regulatory approval (Italy, UK). Main study endpoint is real-world PFS. Secondary endpoints include overall survival and response rates. The study will also describe surrogate measures of response and tolerability, including time to discontinuation, dose modifications (with reasons) and time to first and second subsequent treatment. Outcomes will be described by key subgroup status pre-index, including performance status, FIGO stage, BRCAm status, debulking surgery outcome and clinical response to chemotherapy. The study aims to include 350 patients. Retrospective data collection began in December 2020 and is planned to end by Q3 2023. As of April 2021, 69 patients have participated.

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UPLIFT (ENGOT-0V67/GOG-3048) A PIVOTAL COHORT OF UPIFITAMAB RILSODOTIN, A NAPI2B-DIRECTED ADC IN PLATINUM-RESISTANT OVARIAN CANCER

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Introduction/Background* Upifitamab rilsodotin (XMT-1536; UpRi), is a first-in-class Dolaflexin antibody-drug conjugate targeting NaPi2b, a sodium-dependent phosphate transport protein broadly expressed in solid tumors including high-grade serous epithelial ovarian cancer (OC). UpRi's safety and efficacy are being evaluated in a Phase I study (NCT03319628). Preliminary antitumor activity from an expansion cohort of heavily-pretreated OC patients has been reported (Hamilton et al, ESMO 2020). A data-cut of December 2020 demonstrated an ORR of 39% including 2 CRs and DCR of 81% in 26 OC patients with high NaPi2b expression (TPS \geq 75). The 2 patients achieving CR had previously been treated with bevacizumab and PARPi (Richardson et al, ASCO 2021, TPS5607). The prevalence of a TPS \geq 75 is greater than 60%.

PROC remains a serious unmet medical need as available treatment options provide modest benefit of no more than 12% ORR and median OS less than 12 months. Based on encouraging anti-tumor activity of UpRi, UPLIFT was designed as a Phase 2 single-arm registration strategy for PROC as part of the ongoing study.

Methodology The UPLIFT cohort is enrolling patients with platinum resistant high grade serous ovarian, fallopian tube

and primary peritoneal cancer with up to 4 prior lines of therapy. Prior bevacizumab is required for patients with 1 or 2 prior lines of therapy but is not required for patients with 3-4 prior lines of therapy. UPLIFT will enroll approximately 180 patients globally for 100 patients with high NaPi2b expression. UpRi is dosed intravenously at 43 mg/m² every 4 weeks. Patients may enroll regardless of NaPi2b expression and regardless of baseline peripheral neuropathy. Baseline tumor samples (fresh or archived) will be collected for retrospective tumor tissue evaluation of NaPi2b expression.

Result(s)* The primary objective is assessment of objective response rate in patients with high NaPi2b expression. The cut-off for high NaPi2b expression is TPS \geq 75 and was based on data from the expansion cohort. Secondary endpoints include objective response rate in the overall population, duration of response, and adverse events.

Conclusion* This study is being conducted in collaboration with ENGOT and GOG. Patients will be enrolled globally. (NCT03319628).

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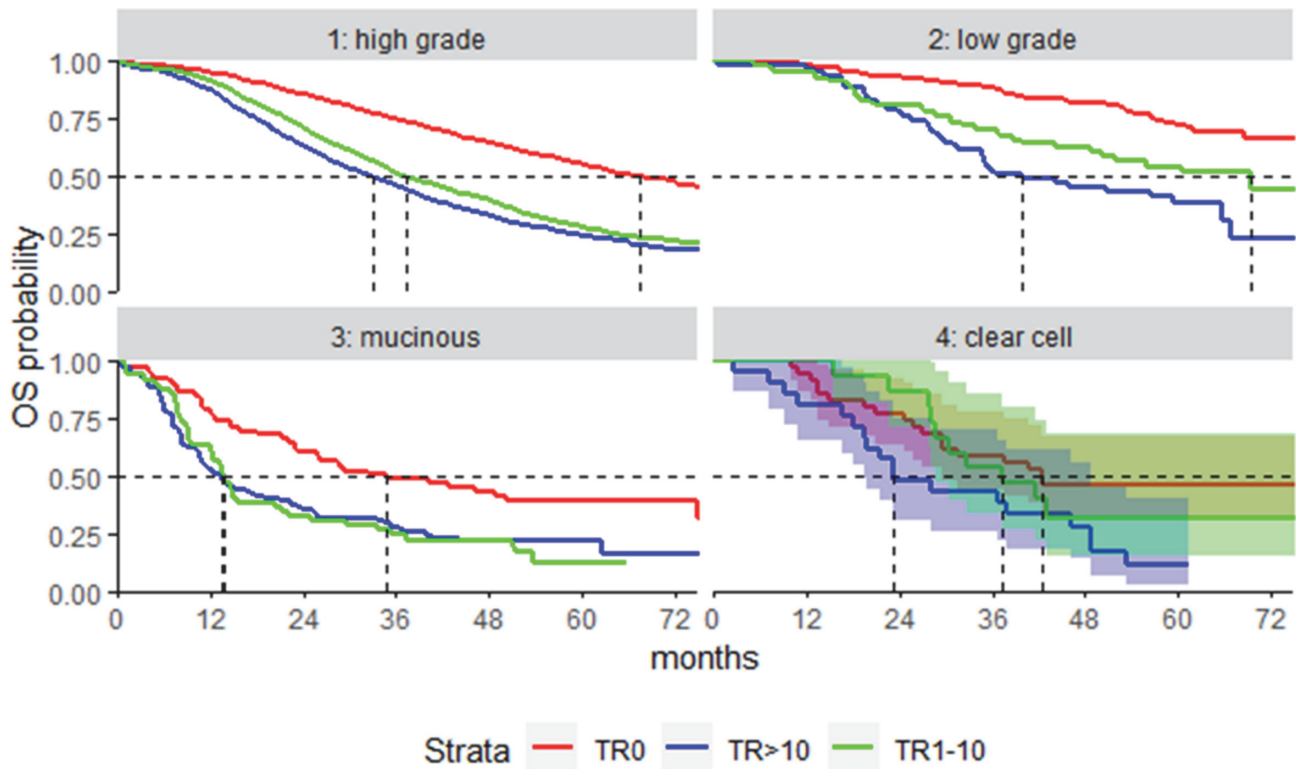
SURGICAL OUTCOME AS PROGNOSTIC FACTOR IN DIFFERENT HISTOLOGIC SUBTYPES OF OVARIAN CARCINOMA- ANALYSIS OF 7 PHASE III TRIALS BY AGO STUDYGROUP + ENGOT

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Introduction/Background* Debulking surgery is the mainstay of treatment for patients (pts) with advanced epithelial ovarian cancer (EOC). Upfront surgery (PDS) with complete macroscopic resection (TR0) is associated with best survival while PDS to small residual disease (TR1-10) provides moderate benefit in high grade serous OC. The impact of resection status in other histological subtypes so far has not been defined and especially the role of TR1-10 is under debate. This analysis should help to better understand the interplay between histological subtype, surgical outcome, and prognosis.

Methodology Data of patients (>FIGO IIIB) from 7 AGO-Studygroup led phase III multicentre trials (AGO-OVAR 3,5,7,9,11,12,15), (1995–2011) were pooled and analysed with focus on PDS resection status on overall survival (OS) in different histological subtypes: low grade (low grade serous or endometrioid), mucinous, clear cell, and high-grade (e.g.



Abstract 186 Figure 1 Kaplan-Meier plots of overall survival within tumour types according to complete (TR0) and largely (TR1-10mm) debulking; number of patients included into the clear cell cohort was too small to allow meaningful OS analyses

Abstract 186 Table 1 OR: odds ratio; OS: overall survival; HR: hazard ratio; *number of patients included into the clear cell cohort was too small to allow meaningful OS analyses

| | High grade | Low grade | Mucinous | Clear cell |
|------------------------------|------------------|------------------|------------------|------------------|
| n | 5,156 | 299 | 219 | 71 |
| TR0 (%) | 32.7% | 52.2% | 31.1% | 49.3% |
| TR1-10 (%) | 31.7% | 26.1% | 26.0% | 21.1% |
| OR (95%CI) for TR0 | 1 (reference) | 1.84 (1.44–2.36) | 0.95 (0.70–1.29) | 1.69 (1.03–2.79) |
| Deaths n (%) | 3,122 (60.6%) | 115 (38.5%) | 155 (70.8%) | 46 (64.8%) |
| OS HR(95%CI) TR0 vs TR>10 | 0.48 (0.43–0.52) | 0.39 (0.24–0.64) | 0.64 (0.40–1.03) | * |
| OS HR(95%CI) TR1-10 vs TR>10 | 0.91 (0.84–0.99) | 0.87 (0.52–1.44) | 1.09 (0.71–1.67) | * |
| OS HR(95%CI) TR0 vs TR1-10 | 0.52 (0.48–0.58) | 0.45 (0.28–0.73) | 0.59 (0.36–0.96) | * |
| OS HR(95%CI) TR0 vs TR>0 | 0.50 (0.46–0.54) | 0.42 (0.28–0.64) | 0.62 (0.40–0.95) | * |

serous, endometrioid, undifferentiated histology). Multiple logistic regression of achieving TR0 in the full population and multiple Cox-regression of OS separately in each histological subpopulation adjusting potential confounders (treatment arm within each study, ECOG performance status, age, FIGO stage) were undertaken.

Result(s)* 5,745 pts were eligible (5,156 high grade, 299 low grade, 219 mucinous, 71 clear cell). Differences in resection rates between histological subtypes are displayed in the table

1. Adjusted odds ratios showed significantly higher odds for achieving TR0 for low grade and clear cell compared to high-grade, (table 1). Median follow-up was 60.7 months. The figure shows OS within tumour types according to resection status. Hazard ratios between TR0, TR1-10 and TR>10 obtained from multiple Cox regression of OS are shown in the table 1.

Conclusion* Our analysis confirmed the value of complete resection in all subtypes of ovarian cancer. The role of largely resection (TR1-10mm) seemed to be relevant in low grade OC, but marginal although significant in HGSOc and inconclusive in mucinous and clear cell OC. Larger databases are necessary to gain more reliable data in these subgroups.

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PLATINUM RESISTANCE IN OVARIAN CARCINOMA LONG-TERM SURVIVORS: A RETROSPECTIVE STUDY AT THE TUEBINGEN UNIVERSITY WOMEN'S HOSPITAL

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Introduction/Background* Despite the majority of ovarian carcinoma patients (OvCa) initially responding to primary therapy, relapse occurs frequently in early and advanced stages (25 and 80% respectively) and OvCa is still associated with an overall poor prognosis. Nevertheless, therapy response and disease progression can be quite variable and long-term survival is reported in up to 30% of patients. It is known that,