# *KURZPROTOKOLL*
# *3000-03-005/ENGOT-OV44 (FIRST)*

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| **Öffentlicher Titel** | Phase III Studie zu Dostarlimab vs. Niraparib als Erstlinienbehandlung bei Ovarialkarzinom (Stadiums III/IV) |
| **Wissenschaftl. Titel** | Ein randomisierter, doppelblinder Phase-III-Vergleich von platinbasierter Therapie mit TSR-042 und Niraparib mit platinbasierter Versorgungsstandardtherapie als Erstlinienbehandlung für nicht muzinöses epitheliales Ovarialkarzinom des Stadiums III oder IV (3000-03-005/ENGOT-OV44) |
| **Kurztitel** | 3000-03-005/ENGOT-OV44 (FIRST) |
| **Studienart** | prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, dreiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Erstlinie |

**Einschlusskriterien**

- Patients with a histologically confirmed diagnosis of high-grade nonmucinous epithelial ovarian (serous, endometrial, clear cell, carcinosarcoma, an mixed pathologies), fallopian tube, or primary peritoneal cancer that is Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) or tumor, node and metastasis staging criteria
- All patients with Stage IV disease are eligible. This includes those with inoperable disease, those who undergo primary debulking surgery (complete cytoreduction (CC0) or macroscopic disease), or those for whom neoadjuvant chemotherapy is planned
- Patients with Stage III are eligible if they meet one or more of the following criteria: High risk Stage IIIC disease. Planning to receive neoadjuvant chemotherapy
- Patients must provide a blood sample for research at Screening
- Patient must provide sufficient tumor tissue sample (a minimum of 2 formalin-fixed paraffin embedded blocks) at Screening for research
- Patients must have adequate organ function (Note: complete blood count test should be obtained without transfusion or receipt of stimulating factors within 2 weeks before obtaining Screening blood sample)
- Patients must have an ECOG score of 0 or 1
- Patients must have normal blood pressure (BP) or adequately treated and controlled hypertension (systolic BP <=140 mmHg and/or diastolic BP <=90 mmHg)
- Patients must agree to complete HRQoL questionnaires throughout the study
- Patients must be able to take oral medication

**Ausschlusskriterien**

- Patient has mucinous, germ cell, transitional cell, or undifferentiated tumor
- Patient has low-grade or Grade 1 epithelial ovarian cancer
- Stage III patient with complete cytoreduction (CC0) resection after primary debulking surgery (ie, no macroscopic residual disease, unless the patient has aggregate 5 cm extra-pelvic disease during primary debulking surgery
- Patient has not adequately recovered from prior major surgery
- Patient has a known condition, therapy, or laboratory abnormality that might confound the study results or interfere with the patient's participation for the full duration of the study treatment in the opinion of the Investigator
- Patient has been diagnosed and/or treated with any therapy for invasive cancer <5 years from study enrollment, completed adjuvant chemotherapy and/or targeted therapy (eg, trastuzumab) less than 3 years from enrollment, or completed adjuvant hormonal therapy less than 4 weeks from enrollment. Patients with definitively treated non-invasive malignancies such as cervical carcinoma in situ, ductal carcinoma in situ, Grade 1 or 2, Stage IA endometrial cancer, or non-melanomatous skin cancer are allowed

- Patient is at increased bleeding risk due to concurrent conditions (eg, major injuries or major surgery within the past 28 days prior to start of study treatment and/or history of hemorrhagic stroke, transient ischemic attack, subarachnoid hemorrhage, or clinically significant hemorrhage within the past 3 months)
- Patient is immunocompromised. Patients with splenectomy are allowed. Patients with well-controlled known human immunodeficiency virus (HIV) are allowed
- Patient has known active hepatitis B (eg, hepatitis B surface antigen reactive) or hepatitis C (eg, hepatitis C virus ribonucleic acid [qualitative] is detected)
- Patient is considered a poor medical risk due to a serious, uncontrolled medical disorder, non-malignant systemic disease, or active, uncontrolled infection
- Patient has had investigational therapy administered within 4 weeks or within a time interval less than at least 5 half-lives of the investigational agent, whichever is longer, prior to the first scheduled day of dosing in this study
- Patient has received a live vaccine within 14 days of planned start of study therapy. Seasonal influenza vaccines that do not contain live viruses are allowed
- Patient has a known contraindication or uncontrolled hypersensitivity to the components of paclitaxel, carboplatin, niraparib, bevacizumab, dostarlimab, or their excipients
- Prior treatment for high-grade nonmucinous epithelial ovarian, fallopian tube, or peritoneal cancer (immunotherapy, anti-cancer therapy, radiation therapy)
- Patient has an active autoimmune disease that has required systemic treatment in the past 2 years. Replacement therapy is not considered a form of systemic therapy (eg, thyroid hormone or insulin)
- Patient has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of systemic immunosuppressive therapy within 7 days prior to the first dose of study treatment

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| **Alter** | 18 Jahre und älter |
| **Sponsor** | TESARO |
| **Registrierung in anderen Studienregistern** | EudraCT 2018-000413-20<br>ClinicalTrials.gov NCT03602859 (primäres Register) |