KURZPROTOKOLL
Tesaro Ruby

Öffentlicher Titel	Phase III Studie zu Dostarlimab als Erstlinientherapie bei wiederkehrendem oder fortgeschrittenem Gebährmutterkrebs
Wissenschaftl. Titel	Eine randomisierte, doppelblinde, multizentrische Phase-3-Studie mit Dostarlimab (TSR-042) plus Carboplatin-Paclitaxel im Vergleich zu Placebo plus Carboplatin-Paclitaxel bei Patienten mit rezidivierendem oder primär fortgeschrittenem Endometriumkarzinom
Kurztitel	Tesaro Ruby
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Gebärmutterschleimhautkrebs (Endometriumkarzinom) - Erstlinie Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Gebärmutterschleimhautkrebs (Endometriumkarzinom) - Zweitlinie oder höher
Einschlusskriterien	- Part 1 and Part 2: - 1. Female participant is at least 18 years of age - 2. Participant has histologically or cytologically proven endometrial cancer with recurrent or advanced disease - 3. Participant must have primary Stage III or Stage IV disease or first recurrent endometrial cancer with a low potential for cure by radiation therapy or surgery alone or in combination and meet at least one of the following criteria: - 3a. Participant has primary Stage IIIA to IIIC1 disease with presence of evaluable or measurable disease per RECIST v.1.1 based on Investigator's assessment. Lesions that are equivocal or can be representative of post-operative change should be biopsied and confirmed for the presence of tumor - 3b. Participant has primary Stage IIIC1 disease with carcinosarcoma, clear cell, serous, or mixed histology (containing >=10 percent carcinosarcoma, clear cell, or serous histology) regardless of presence of evaluable or measurable disease on imaging - 3c. Participant has primary Stage IIIC2 or Stage IV disease regardless of the presence of evaluable or measurable disease - 3d. Participant has first recurrent disease and is naïve to systemic anticancer therapy - 3e. Participant has received prior neo-adjuvant/adjuvant systemic anticancer therapy and had a recurrence or PD >=6 months after completing treatment (first recurrence only) - 4. Participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 - 5. Participant has adequate organ function - Part 2 only: - 1. Participants must have normal blood pressure (BP) or adequately treated and controlled hypertension (systolic BP <=140 millimeter of mercury (mmHg) and diastolic BP <=90 mmHg) - 2. Participants must be able to take medication orally, by mouth (PO)
Ausschlusskriterien	- Part 1 and Part 2: - 1. Participant has received neo-adjuvant/adjuvant systemic anticancer therapy for primary Stage III or IV disease and: - 1a. has not had a recurrence or PD prior to first dose on the study OR - 1b. has had a recurrence or PD within 6 months of completing systemic anticancer therapy treatment prior to first dose on the study - 2. Participant has had >1 recurrence of endometrial cancer

	- 3. Participant has received prior therapy with an anti-programmed cell death protein 1 (anti-PD-1), anti-PD-ligand 1 (anti-PD-L1), or anti-PD-ligand 2 (anti-PD-L2) agent - 4. Participant has received prior anticancer therapy (chemotherapy, targeted therapies, hormonal therapy, radiotherapy, or immunotherapy) within 21 days or <5 times the half-life of the most recent therapy prior to Study Day 1, whichever is shorter - 5. Participant has a concomitant malignancy, or participant has a prior non-endometrial invasive malignancy who has been disease-free for <3 years or who received any active treatment in the last 3 years for that malignancy. Non-melanoma skin cancer is allowed - 6. Participant has known uncontrolled central nervous system metastases, carcinomatosis meningitis, or both - 7. Participant has not recovered (i.e., to Grade <=1 or to Baseline) from cytotoxic therapy induced AEs or has received transfusion of blood products (including platelets or red blood cells) or administration of colony-stimulating factors (including granulocyte colony-stimulating factor [G-CSF], granulocyte macrophage colony-stimulating factor [GM-CSF], or recombinant erythropoietin) within 21 days prior to the first dose of study drug - 8. Participant is considered a poor medical risk due to a serious, uncontrolled medical disorder, nonmalignant systemic disease, or active infection requiring systemic therapy - 9. Participant has received, or is scheduled to receive, a live vaccine within 30 days before first dose of study treatment, during study treatment, and for up to 180 days after receiving the last dose of study treatment - Part 2 only: - 1. Participant has clinically significant cardiovascular disease - 2. Participant has any known history or current diagnosis of myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML) - 3. Participant is at increased bleeding risk due to concurrent conditions - 4. Participant has participated in Part 1 of this study
Alter	18 Jahre und älter
Sponsor	Tesaro, Inc.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03981796 EudraCT 2019-001576-11 (primäres Register)