Dostarlimab “A Miracle Drug Against Cancer”: Current Knowledge and On-going Clinical Trials

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Abstract
Cancer stands as one of the leading causes of death globally. Its socio-economic burden is increasing day by day. There is no defined treatment strategy for cancer. In most of the cases a combinatorial therapy approach is utilised which includes surgery, chemotherapy, immune therapy, radiation therapy etc. Immune checkpoints are a revolutionary discovery in cancer immunotherapy. Dostarlimab is an anti-programmed cell death protein-1 (PD-1) immunoglobulin G4 (IgG4) humanised monoclonal antibody (mAb), produced by recombinant DNA technology in mammalian Chinese hamster ovary (CHO) cells. PD-1 is an immune checkpoint receptor expressed by T-cells which has shown to suppress cancer-specific immune responses. In this article we provide the recent known information regarding dostarlimab along with currently undergoing 44 clinical trials globally with its title, conditions, interventions, and outcome measures.

Keywords: Dostarlimab, Locally advanced rectal cancer; Mismatch repair deficient (dMMR) recurrent or advanced solid tumors; GARNET trial; Monoclonal antibodies; Cancer immunotherapy; Clinical trials

Abbreviations
dMMR: Mismatch repair deficient; WHO: World Health Organization; PD-L1: Programmed cell death ligand 1; mAbs: Monoclonal antibodies; CHO: Chinese hamster ovary; GSK: GlaxoSmithKline; PD-1: Programmed death-1; MRI: Magnetic Resonance Imaging.

Introduction
Cancer stands as one of the leading causes of death around the world with variable rate of mortality in different regions of the world [1]. Cancer burden is increasing over time in both developed and developing nations. The reason behind this is complex which involves aging, population explosion, socio-economic issues, and changes in the occurrence of associated risk factors [2,3]. Cancer is causing premature death and influencing life expectancy in many countries. As per WHO nearly 10 million deaths were reported in 2020 globally [4]. The most common type of cancer reported were breast, lung, colon, rectum and prostate cancers. Alone colon and rectum cancer were reported for around 1.93 million cases with approximately 1 million reported deaths.

There is no defined treatment strategy for cancer. It depends on cancer type and its advancement. Very rarely one-line treatment is done. Most of the cancer patient receives a combination of treatments which includes surgery, chemotherapy, radiation therapy, hormone therapy, immunotherapy, phytotherapy and targeted therapy. Immune therapy involves boosting the immune system to fight cancer. Immune therapy has been approved to treat different types of cancers which includes colorectal cancer, cervical cancer, breast cancer, head and neck cancer, bladder cancer, kidney cancer, leukemia, lung cancer,
lymphoma, prostate cancer, skin cancer etc. All patients with these cancers are not eligible for immunotherapy. Immunotherapy depends upon the genetic makeup of the tumor cells, advancement in cancer and previous response to treatments [5].

In immunotherapy currently researchers are looking to find solution for resistance. Thus, different combinations of immune check point inhibitors are being extensively studied [6]. Immune checkpoints are a revolutionary discovery in cancer immunotherapy. The interaction between programmed cell death ligand 1 (PD-L1) and its receptor, programmed cell death (PD-1), inhibits the immune response and has been shown to be crucial for self-tolerance, immune evasion, and autoimmunity avoidance [7].

**Monoclonal Antibodies (mAbs)**

Monoclonal Antibodies (mAbs) are considered as efficient therapeutic agents in immune-oncology. However, despite their success, the glitches in their clinical application in all patients is a matter of concern. Among these the development of immunogenicity due to formation of antidrug antibodies against exogenous therapeutics is one of them [8]. The antidrug antibodies have the potential to alter the pharmacokinetics, safety and efficacy of drugs. Patient related factors like (e.g., human leukocyte antigen type, immune competence, disease, concomitant medicines), dose regimen, route of administration, and critical product factors (e.g., primary sequence, T and B cell epitopes, expression system, glycosylation, aggregation, degradation, post-translational modification, formulation, and impurities influence the development of antidrug antibodies [9]. Antidrug antibodies alter the drug clearance and impact the drug safety through infusion reactions, anaphylaxis, hypersensitivity reactions and ADA-mediated diseases [10]. Neutralizing antibodies are a type of antidrug antibodies which reduces the efficacy by disrupting targeted binding of drug. Humanization of antibodies reduces the risk of immunological responses; however, they are still observed with partially or fully humanized antibodies [11].

**Dostarlimab as PD-1 inhibitor in cancer immunotherapy**

Dostarlimab is an anti-programmed cell death protein-1 (PD-1) immunoglobulin G4 (IgG4) humanised monoclonal antibody (mAb), produced by recombinant DNA technology in mammalian Chinese hamster ovary (CHO) cells [12]. PD-1 is an immune checkpoint receptor expressed by T-cells has been shown to suppress cancer-specific immune responses. Dostarlimab binds to and inhibits PD-1, as well as block the interaction of programmed cell death receptor ligands 1 and 2 (PD-L1 and PD-L2) with the receptor, thus restoring immune function by activating T cells. The monoclonal antibody was developed by AnaptysBio Inc. In the year, 2014 TESARO Inc. entered into exclusive worldwide agreement with AnaptysBio Inc to develop immune-oncology antibodies. Later TESARO was acquired by GlaxoSmithKline (GSK) and thus all these companies came under the umbrella of GSK. Dostarlimab is undergoing a number of clinical trials for various types of cancers like fallopian tube cancer, non-small cell and small cell lung cancer, endometrial cancer, squamous cell cancer, head and neck cancer etc [12].

**FDA approval for mismatch repair deficient (dMMR) recurrent or advanced solid tumors**

In the mid of August, 2021, the U.S.FDA granted accelerated approval for dostarlimab-gxly under the brand name Jemperli, for GlaxoSmithKline LLC for adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors at 500 mg for 3 weeks for first four dosage as i.v. infusion over 30 minutes. Subsequent dosing beginning 3 weeks after 4 doses is 1 g every 6 weeks. The approval was supported by the GARNET trial (NCT02715284). The study was a non-randomized, multicentre, open-label, multi-cohort trial [13]. It was further approved in Europe also [14].

The study evaluated objective response rate and duration of response using response evaluation criteria in solid tumors, version 1.1. The ORR was 41.6% with 9.1% complete response rate and 32.5% partial response rate. Median DOR was 34.7 months (range 2.6, 35.8+), with 95.4% of patients with duration ≥6 months. The study further reports anemia, fatigue, sepsis and acute kidney injury as common adverse effects (>20%) [15]. Immune-mediated adverse reactions are also associated with dostarlimab-gxly including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and dermatologic toxicity [15].

**Dostarlimab outstanding result in the treatment of locally advanced rectal cancer**

The first line of treatment for locally advanced rectal cancer includes neo adjuvant chemotherapy along with radiation which is followed by surgical resection of the rectum. It is known that a subset of rectal cancer is caused by deficiency in mismatch repair. The mismatch repair-deficient colorectal cancer is responsive to PD-1 (programmed death-1) blockade, the NCT04165772 clinical trial exploited checkpoint blockade for possible results in patients with mismatch repair-deficient locally
advanced rectal cancer [16]. A total of 12 patients completed the study with a single agent dostarlimab, which was administered every three weeks for 6 months. All the patients were followed up for next 6 months. The researchers reported 100% complete response with no evidence of tumor in any patient which was confirmed by MRI, 18F-fluorodeoxyglucose-positron-emission tomography, endoscopic evaluation, digital rectal examination and biopsy. The researchers further confirmed that no patient had received chemotherapy or have undergone surgery. The results of dostarlimab in the treatment of locally advanced rectal cancer has taken the scientific world by storm as there is no evidence for any other drug or monoclonal antibody which has given 100% complete response in the treatment of any type of cancer in the past. Although the study trial was conducted on small population, but still the promising result makes Dostarlimab a unique drug with potential future [16].

There are currently around 44 trials being conducted using Dostarlimab on different cancer types (Table 1). Table 1 is listed at the last of this article.

**Conclusion**

Cancer stands as one of the leading causes of death. Its socio-economic burden is increasing day by day. There is no defined treatment strategy for cancer. In most of the cases a combinatorial therapy approach is utilised. Until now there was no reported clinical trial which claims 100% clinical success in any type of cancer. Dostarlimab has achieve a unique feat in cancer research. Although the success report was in small subject size. Still the results are overwhelming and provides a strong base for future applications of dostarlimab and other immunotherapeutic agents. It is still early to conclude about dostarlimab success against advanced rectal cancer. There are currently around 44 clinical trials around the world are going on dostarlimab. Further research outcomes will enlighten us with more information regarding their possible clinical application and associated risks.

**Conflict of Interest**

The author declares no conflict of interest.

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24. https://ClinicalTrials.gov/show/NCT04409002
25. https://ClinicalTrials.gov/show/NCT05201547
26. https://ClinicalTrials.gov/show/NCT04701307
27. https://ClinicalTrials.gov/show/NCT03955471
28. https://ClinicalTrials.gov/show/NCT04581824
29. https://ClinicalTrials.gov/show/NCT05126342
30. https://ClinicalTrials.gov/show/NCT04926324
31. https://ClinicalTrials.gov/show/NCT04940637
32. https://ClinicalTrials.gov/show/NCT04983745
33. https://ClinicalTrials.gov/show/NCT04679064
34. https://ClinicalTrials.gov/show/NCT04493060
35. https://ClinicalTrials.gov/show/NCT03981796
36. https://ClinicalTrials.gov/show/NCT04779151
37. https://ClinicalTrials.gov/show/NCT04895046
38. https://ClinicalTrials.gov/show/NCT03680508
39. https://ClinicalTrials.gov/show/NCT04837209
40. https://ClinicalTrials.gov/show/NCT03806049
41. https://ClinicalTrials.gov/show/NCT04681469
42. https://ClinicalTrials.gov/show/NCT04584255
43. https://ClinicalTrials.gov/show/NCT03843359
44. https://ClinicalTrials.gov/show/NCT04446351
45. https://ClinicalTrials.gov/show/NCT03602859
46. https://ClinicalTrials.gov/show/NCT04165772
47. https://ClinicalTrials.gov/show/NCT05277051
48. https://ClinicalTrials.gov/show/NCT03308942
49. https://ClinicalTrials.gov/show/NCT03250832
50. https://ClinicalTrials.gov/show/NCT02723955
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57. https://ClinicalTrials.gov/show/NCT01042379
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# Table 1: List of undergoing clinical trials on dostarlimab for possible application in different types of cancer.

| NCT Number   | Title                                                                 | Conditions                                                      | Interventions       | Outcome Measures                                                                 | Sponsor/Collaborators                  | Phases | References |
|--------------|-----------------------------------------------------------------------|-----------------------------------------------------------------|---------------------|---------------------------------------------------------------------------------|----------------------------------------|--------|------------|
| NCT05239546 | Single Arm Study of Neoadjuvant Dostarlimab in Stage II and III Deficient Mismatch Repair Colon Cancers | Colon Cancer; DMMR Colorectal Cancer                             | Drug: Dostarlimab   | Percentage change in viable tumor cells (VTC); Determine metastatic disease rate (MDR); Determine disease free survival (DFS); Determine overall response rate (ORR) | University of Iowa                     | Phase 2 | 17         |
| NCT05405192 | Dostarlimab in Chemoresistant Gestational Trophoblastic Neoplasia    | Gestational Trophoblastic Neoplasia                              | Drug: Dostarlimab   | Proportion of patients with successful normalization of beta hCG; Proportion of patients with objective response rate (ORR); Number of Participants with treatment related-adverse events; Progression-free survival (PFS); Overall survival (OS) | University of Miami; GlaxoSmithKline   | Phase 2 | 18         |
| NCT04313504 | Study Evaluating the Efficacy of Niraparib and Dostarlimab (TSR-042) in Recurrent/Metastatic HNSCC | Head and Neck Cancer                                              | Drug: Niraparib; Drug: Dostarlimab | Overall Response; Rate of all Adverse Events; Progression Free Survival; Overall Survival | Trisha Wise-Draper; GlaxoSmithKline; University of Cincinnati | Phase 2 | 19         |
| NCT04068753 | Niraparib in Combination with Dostarlimab in Patients with Recurrent or Progressive Cervix Cancer | Recurrent Cervix Cancer; Progressive Cervix Cancer                | Drug: Niraparib; Drug: Dostarlimab | Proportion of patients with response to treatment; Number of patients who experience toxicity; Duration of patients with response; Progression free survival; Overall survival | University of Oklahoma; Tesaro, Inc.   | Phase 2 | 20         |
| NCT Number   | Title                                                                 | Conditions                      | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                      | Phases | References |
|--------------|----------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------|--------|------------|
| NCT04139902  | Neoadjuvant PD-1 Inhibitor Dostarlimab (TSR-042) vs. Combination of Tim-3 Inhibitor Cobolimab (TSR-022) and PD-1 Inhibitor Dostarlimab (TSR-042) in Melanoma | Melanoma Stage III; Melanoma Stage IV | Drug: Dostarlimab (TSR-042) (singly); Drug: Dostarlimab (TSR-042) and TSR-022 (combination) | Major Pathologic Response (MPR); Number of Participants Experiencing Adverse Events Attributed to Treatment; Frequency of Delays in Surgery; Frequency of Cancellations of Surgery; Relapse-free Survival; Overall Survival (OS) | Diwakar Davar; Tesaro, Inc.; University of Pittsburgh | Phase 2 | 21         |
| NCT04544995  | Dose Escalation and Cohort Expansion Study of Niraparib and Dostarlimab in Pediatric Participants With Solid Tumors (SCOOP) | Neoplasms                       | Drug: Niraparib; Drug: Dostarlimab                                            | Part 1A: Number of participants with dose limiting toxicities (DLTs); Part 1B: Number of participants with DLTs; Part 2: Progression-free survival rate at 6 months (PFS6) in participants with osteosarcoma; Part 2: Overall response rate (ORR) in participants with neuroblastoma; ORR; Duration of response (DOR); Disease control rate (DCR) in participants; PFS in participants; Number of participants with Treatment emergent adverse events (TEAEs), adverse events (AEs, Serious AEs (SAEs), immune-related AEs (irAEs), TEAEs leading to death and AEs | GlaxoSmithKline                             | Phase 1 | 22         |
| NCT Number   | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators   | Phases       | References |
|--------------|-----------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------|--------------|------------|
| NCT04655976 | Efficacy Comparison of Cobolimab + Dostarlimab + Docetaxel to Dostarlimab + Docetaxel to Dostarlimab + Docetaxel to Docetaxel Alone in Participants With Advanced Non-Small Cell Lung Cancer Who Have Progressed on Prior Anti-Programmed Death-ligand 1 (PD-[L]1) Therapy and Chemotherapy | Lung Cancer, Non-Small Cell                                                 | Biological: Cobolimab; Biological: Dostarlimab; Drug: Docetaxel                 | leading to discontinuation; Plasma concentration of niraparib; Serum concentration of dostarlimab; Number of participants compliant based on 'Acceptability and Palatability questionnaire' | GlaxoSmithKline      | Phase 2;    |            |
|              |                                                                       |                                                                             |                                                                                 |                                                                                  |                        | Phase 3      |            |

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| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            |               | assessment; Change from Baseline in the EORTC QLQ LC13 assessment; Number of participants with serious adverse events (SAEs); Number of participants with treatment-emergent adverse events (TEAEs) and immune related adverse event (irAEs); Number of participants with TEAEs leading to death; Number of participants with adverse events (AEs) leading to discontinuation; Number of participants with clinically significant changes in hematology, clinical chemistry, thyroid function and urinalysis lab parameters; Number of participants with clinically significant changes in vital signs and Electrocardiogram (ECG) Parameters; Number of participants with indicated Eastern Cooperative Oncology Group (ECOG) performance status; Number of participants with usage of concomitant medications; Number of participants with abnormal physical examinations |                      |          |            |
| NCT Number   | Title                                                                 | Conditions                                      | Interventions                               | Outcome Measures                                                                 | Sponsor/ Collaborators                      | Phases | References |
|-------------|-----------------------------------------------------------------------|------------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------|--------|------------|
| NCT04409002 | Niraparib + Dostarlimab + RT in Pancreatic Cancer                     | Pancreatic Cancer; Metastatic Pancreatic Cancer | Drug: Niraparib; Drug: Dostarlimab; Radiation: Radiation | Disease control rate with RECIST 1.1; Disease control rate with rRECIST; Progression-free survival; Overall survival; Number of Participants With Treatment-Related Adverse Events CTCAE.v 5.0 | Massachusetts General Hospital; Tesaro, Inc. | Phase 2 | 24         |
| NCT05201547 | Endometrial Cancer Patients MMR Deficient Comparing Chemo vs Dostarlimab in First Line | Endometrial Cancer                              | Drug: Carboplatin-Paclitaxel; Drug: Dostarlimab | Progression Free Survival (PFS); Quality Of Life evaluation based on EORTC QLQ-C30 (Quality Of Life Questionnaire-core 30); Quality Of Life evaluation based EORTC QLQ-EN24 (Quality of Life Questionnaire - Endometrial Cancer Module); Quality Of Life evaluation based on Quality of Life Questionnaire EQSD5L (The 5-level EQ-SD version); Quality Of Life evaluation based on Quality of Life Questionnaire I-ADL Scale (Index of Independence in Activities of Daily Living); Quality Of Life evaluation based on Quality of Life Questionnaire CIPN20 (Chemotherapy-induced peripheral neuropathy); Objective Response Rate; | ARCAGY/GINECO GROUP; GlaxoSmithKline       | Phase 3 | 25         |
| NCT Number  | Title                                                                 | Conditions                                                                 | Interventions                       | Outcome Measures                                                                 | Sponsor/ Collaborators | Phases | References |
|-------------|------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------|---------------------------------------------------------------------------------|------------------------|--------|------------|
| NCT04701307 | Niraparib and Dostarlimab for the Treatment of Small Cell Lung Cancer and Other High-Grade Neuroendocrine Carcinomas | Lung Small Cell Carcinoma; Neuroendocrine Carcinoma; Stage III Lung Cancer AJCC v8; Stage IIIA Lung Cancer AJCC v8; Stage IIIB Lung Cancer AJCC v8; Stage IIIC Lung Cancer AJCC v8 | Biological: Dostarlimab; Drug: Niraparib | Duration of Response Rate; Overall Survival; Safety evaluation; Time to first and second subsequent treatment | M.D. Anderson Cancer Center | Phase 2 | 26         |
| NCT03955471 | Study to Evaluate the Efficacy and Safety of the Combination of Niraparib and Dostarlimab (TSR-042) in Participants With Platinum Resistant Ovarian Cancer | Ovarian Neoplasms                                                                 | Drug: Niraparib; Drug: Dostarlimab | Objective Response Rate (ORR); Duration of Response (DOR); Progression-free Survival (PFS); Overall Survival (OS); Disease Control Rate (DCR); ORR Based on Independent Review Committee Assessment; DOR based on Independent Review Committee Assessment; PFS based on Independent Review Committee Assessment; DCR based on Independent Review Committee Assessment; Number of participants with adverse events (AEs), serious adverse events (SAEs) | Tesaro, Inc.; Gynecologic Oncology Group | Phase 2 | 27         |
### Table of Clinical Trials

| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|------------------------|--------|------------|
| NCT04581824 | Efficacy Comparison of Dostarlimab Plus Chemotherapy Versus Pembrolizumab Plus Chemotherapy in Participants With Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) | Lung Cancer, Non-Small Cell | Drug: Dostarlimab; Drug: Pembrolizumab; Drug: Chemotherapy | adverse events (SAEs) and adverse event of special interest (AESI); Number of participants with clinically significant changes in vital signs, hematology, plasma chemistry, coagulation and thyroid function | GlaxoSmithKline | Phase 2 | 28 |
### Table 1: Clinical Trials

| NCT Number   | Title                                                                 | Conditions                                                                 | Interventions            | Outcome Measures                                                                 | Sponsor/Collaborators                     | Phases | References |
|--------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------|----------------------------------------------------------------------------------|-------------------------------------------|--------|------------|
| NCT05126342 | Study to Estimate Efficacy of Combining Dostarlimab and Niraparib in Relapsed EOC After Treatment With PARPi | Recurrent Ovarian Cancer; Recurrent Fallopian Tube Cancer; Primary Peritoneal Cancer | Drug: Niraparib; Drug: Dostarlimab | urinalysis lab parameters.; Number of participants with abnormal vital signs; Number of participants with abnormal Eastern Cooperative Oncology Group (ECOG) performance status; Number of participants with abnormal electrocardiogram (ECG) parameters; Number of participants with abnormal physical examination; Number of participants receiving concomitant medications | AGO Research GmbH; GlaxoSmithKline        | Phase 2 | 29         |
| NCT04926324 | A Safety Study Adding Niraparib and Dostarlimab to Radiation Therapy for Rectal Cancers | Rectal Neoplasms; Rectal Neoplasm Malignant | Drug: Niraparib; Drug: Dostarlimab; Radiation: Short course radiation | Determination of recommended phase 2 niraparib dose; Determination of the pathologic complete response; Determination of the clinical complete response rate; Determine overall survival (OS); Determine progression | Joseph Caster, Ph.D., M.D.; GlaxoSmithKline; University of Iowa | Phase 1; Phase 2 | 30         |
| NCT Number     | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                                                                                                                                                 | Sponsor/Collaborators                      | Phases | References |
|--------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------|-------------|
| NCT04940637 | UNITO-001-A Phase II Study in HRR/PDL1 Positive MPM/NSCLC             | Lung Cancer; Mesothelioma                                                   | Drug: niraparib and dostarlimab                                               | free survival (PFS); Determine metastasis free survival; Determine local recurrence free survival; Determine ostomy free survival; Determine objective response rate                                                                 | University of Turin, Italy                | Phase 2 | 31          |
| NCT04983745 | Niraparib and Dostarlimab in HRD Solid Tumors                        | Homologous Recombination Deficient Solid Tumors                             | Drug: Combination drug                                                        | PFS; Objective response rate; Disease control rate; Duration of response; Overall survival                                                                                                                      | West Cancer Center                        | Phase 2 | 32          |
| NCT04679064 | Trial on NIRaparib-TSR-042 (Dostarlimab) vs Physician's Choice CHeMoTherapy in Recurrent, Ovarian, Fallopian Tube or Primary Peritoneal Cancer Patients Not Candidate for Platinum Retreatment | Ovarian Cancer                                                              | Drug: Niraparib; Drug: Dostarlimab; Drug: Pegylated liposomal doxorubicin; Drug: Paclitaxel; Drug: Gemcitabine; Drug: Topotecan; Drug: Bevacizumab | Overall Survival; Progression free survival; Time to first subsequent therapy; Response rate; Number and type of adverse events; Patient-reported outcomes for physical well-being; Patient-reported outcomes for social/family well-being; Patient-reported outcomes for emotional well-being | Fondazione Policlinico Universitario Agostino Gemelli IRCCS; GlaxoSmithKline | Phase 3 | 33          |
| NCT04493060 | Niraparib and Dostarlimab for the Treatment of Germline or             | Metastatic Pancreatic Ductal Adenocarcinoma; Stage IV                       | Biological: Dostarlimab; Drug: Niraparib                                     | Disease control rate at 12 weeks (DCR12); Objective response rate (ORR); Time to next treatment (TTNT);                                                                                                          | Mayo Clinic; National Cancer Institute (NCI) | Phase 2 | 34          |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|------------------------|--------|------------|
|            | Somatic BRCA1/2 and PALB2 Mutated Metastatic Pancreatic Cancer | Pancreatic Cancer AJCC v8 | Biological: Dostarlimab; Drug: Placebo matching dostarlimab; Drug: Carboplatin; Drug: Paclitaxel; Drug: Niraparib; Drug: Placebo matching Niraparib | Overall survival (OS); Time to and duration of confirmed response; Progression-free survival (PFS); Incidence of adverse events (AEs) | Tesaro, Inc.; European Network of Gynaecological Oncological Trial Groups (ENGOT); GOG Foundation | Phase 3 | 35 |
| NCT03981796 | A Study to Evaluate Dostarlimab Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Participants With Recurrent or Primary Advanced Endometrial Cancer | Neoplasms | | Parts 1 and 2: Progression-Free Survival (PFS) - investigator assessment; Part 1: Overall survival; Part 2: Overall survival; Parts 1 and 2: Progression free survival (PFS) blinded independent central review (BICR); Parts 1 and 2: Objective response rate (ORR) - BICR and Investigator assessment; Parts 1 and 2: Duration of response (DOR) - BICR and Investigator assessment; Parts 1 and 2: Disease control rate (DCR) - BICR and Investigator assessment; Parts 1 and 2: Patient-reported outcomes (PROs) in the European Quality of Life scale, 5-Dimensions, 5-Levels (EQ-5D-5L); Parts 1 and 2: PROs in the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30 [Core]); Parts 1 and 2: PROs in | | | |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            |       |            |               | the EORTC Quality of Life Questionnaire (Endometrial Cancer Module [QLQ-EN24]); Parts 1 and 2: Progression-free survival 2 (PFS2); Parts 1 and 2: Number of participants with adverse events (AEs), Serious adverse events (SAEs) and treatment-emergent adverse events (TEAEs); Parts 1 and 2: Number of participants with clinically significant changes in clinical laboratory parameters, physical examination, electrocardiogram (ECG) and participants reporting the intake of concomitant medication; Parts 1 and 2: Change from Baseline in vital sign: Diastolic Blood Pressure (DBP) and Systolic Blood Pressure (SBP) (Millimeters of mercury); Parts 1 and 2: Change from Baseline in vital sign: Heart Rate; Parts 1 and 2: Change from Baseline in vital sign: Respiratory rate; Parts 1 and 2: Change from Baseline in vital sign: Body temperature; Parts 1 and 2: Number of participants with |
| NCT Number  | Title                                                                 | Conditions                                                                 | Interventions | Outcome Measures                                                                                                                                                                                                 | Sponsor/Collaborators                        | Phases | References |
|------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------|------------|
| NCT04779151 | Basket Trial Exploring the Efficacy and Safety of the Combination of Niraparib and Dostarlimab | Urothelial Bladder Cancer; Gastric Adenocarcinoma; Gastro-oesophageal Adenocarcinoma; Head and Neck Cancer; Biliary Tract Cancer; Platinum-sensitive Urothelial Bladder Cancer; Clear Cell | Drug: Dostarlimab; Drug: Niraparib | Overall Response Rate (ORR)                                                                                                                                                                                      | Gustave Roussy, Cancer Campus, Grand Paris   | Phase 2 | 36         |
| NCT Number   | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                                                                                  | Sponsor/Collaborators                                                                 | Phases | References |
|-------------|-----------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------|------------|
| NCT04895046 | Maintenance Niraparib and Dostarlimab in Advanced Cholangiocarcinoma | HRD; Cholangiocarcinoma; Metastatic Cancer                                  | Drug: Niraparib; Drug: Dostarlimab                                             | Progression Free Survival (PFS); Objective Response Rate (ORR); Overall Survival (OS); Duration of Response (DOR); Disease Control Rate (DCR); Frequency and Severity of Adverse Events | Walid Shaib, MD; Emory University; GlaxoSmithKline; Hoosier Cancer Research Network | Phase 2 | 37         |
| NCT03680508 | TSR-022 (Anti-TIM-3 Antibody) and TSR-042 (Anti-PD-1 Antibody) in Patients With Liver Cancer | Adult Primary Liver Cancer; Advanced Adult Primary Liver Cancer; Localized Unresectable Adult Primary Liver Cancer | Drug: TSR-022 and TSR-042                                                     | Objective Response Rate; Objective Response Rate (irRC); Duration of Response; Time to progression; Progression free survival; Overall survival; AFP response; Incidence of Treatment-Emergent Adverse Events as assessed by CTCAE v4.0 | University of Hawaii; GlaxoSmithKline                                                  | Phase 2 | 38         |
| NCT04837209 | Radiation, Immunotherapy and PARP Inhibitor in Triple Negative Breast Cancer | Breast Cancer; Triple Negative Breast Cancer                                | Drug: Niraparib; Drug: Dostarlimab; Radiation: Radiation therapy                | Overall response rate (ORR)-RECIST; Overall response rate (ORR) by irRECIST criteria; Number of Participants With Treatment-Related Adverse Events as Assessed by CTCAE Version 5.0; Overall survival (OS); Progression-free survival (PFS); Change in Quality of Life; Change in PRO-CTCAE; Change in Social Activity Level; Trial Satisfaction | Massachusetts General Hospital; Johns Hopkins University; University of North Carolina; University of Pennsylvania | Phase 2 | 39         |
| NCT Number | Title                                                                 | Conditions                                      | Interventions                                                                 | Outcome Measures                                                                                     | Sponsor/Collaborators                                                                                     | Phases | References |
|------------|----------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------|------------|
| NCT03806049 | Trial Comparing Niraparib-bevacizumab-Dostarlimab and Niraparib-bevacizumab to Standard of Care in Recurrent Ovarian Cancer | Ovarian Cancer                                  | Drug: Niraparib; Drug: Bevacizumab; Drug: TSR042; Drug: Carboplatin; Drug: Paclitaxel | Progression-free Survival; Progression Free Survival in Sub-Population in months; Progression Free Survival 2 in each group according to trial stratification factors; TFST (Time to First Subsequent Therapy); TSST (Time to Second Subsequent Therapy); Overall survival (OS) | Nordic Society of Gynaecological Oncology - Clinical Trials Unit                                         | Phase 3 | 40         |
| NCT04681469 | Induction and Maintenance Treatment With PARP Inhibitor and Immunotherapy in HPV-negative HNSCC                   | Head and Neck Squamous Cell Carcinoma           | Drug: Niraparib                                                               | Rate of Major Pathological Response (Treatment Activity); Incidence of grade 3-5 toxicities (Treatment Safety); Radiological Response; Progression free survival; Radiological and pathological response; Genomic expression | Gruppo Oncologico del Nord-Ovest                                                                  | Phase 2 | 41         |
| NCT04584255 | Niraparib + TSR042 In BRCA Mutated Breast Cancer                                                             | Stage I Breast Cancer; Stage II Breast Cancer; Stage III Breast Cancer; Breast Cancer; HER2-negative Breast Cancer; Germline BRCA1 Gene Mutation; Germline BRCA2 Gene Mutation | Drug: Niraparib; Drug: Dostarlimab                                               | Tumor-infiltrating lymphocytes (TILs); The number and proportion of participants achieving Pathologic Complete Response (pCR); pCR rate (ER+/HER2-BC patients); Changes in TILs; Rate of Residual Cancer Burden (RCB) 0/1 response; Number of Participants With Treatment-Related NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 | Dana-Farber Cancer Institute; Translational Breast Cancer Research Consortium; Johns Hopkins University; GlaxoSmithKline | Phase 2 | 42         |
| NCT Number  | Title                                                                 | Conditions  | Interventions                                      | Outcome Measures                                                                 | Sponsor/Collaborators        | Phases | References |
|------------|-----------------------------------------------------------------------|-------------|----------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------|--------|------------|
| NCT03843359 | Phase 1 First Time in Human (FTIH), Open Label Study of GSK3745417 Administered to Participants With Advanced Solid Tumors | Neoplasms   | Drug: GSK3745417; Drug: Dostarlimab                | Parts 1A and 2A: Number of participants achieving dose-limiting toxicity (DLT); Parts 1A and 2A: Number of participants with adverse events (AEs) and serious adverse events (SAEs) by severity; Part 1A: GSK3745417 concentrations in plasma following administration of GSK3745417 alone; Part 1A: Maximum observed concentration (Cmax) following administration of GSK3745417 alone; Part 1A: Area under the concentration-time curve (AUC) following administration of GSK3745417 alone; Part 1A: Apparent terminal phase half-life (t1/2) following administration of GSK3745417 alone; Part 2A: GSK3745417 concentrations in plasma following administration of GSK3745417 in combination with dostarlimab; Part 2A: Cmax following administration of GSK3745417 in combination with dostarlimab; Part 2A: AUC following administration of GSK3745417 in | GlaxoSmithKline              | Phase 1 | 43         |
### NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|----------------|-----------------|----------------|----------------|----------------|-----------------------------|--------|------------|
| NCT04446351 | Study of the Safety and Effectiveness of GSK6097608 in Participants With Advanced Solid Tumors | Neoplasms | Drug: GSK6097608; Drug: Dostarlimab; Drug: GSK4428859A (EOS884448) | combination with dostarlimab; Part 2A: T1/2 following administration of GSK3745417 in combination with dostarlimab | GlaxoSmithKline; 23andMe, Inc.; iTeos Therapeutics | Phase 1 | 44 |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            |       |            |               | to response (TTR) based on RECIST 1.1; Arms D, E, F: TTR based on iRECIST; Arms D, E, F: Duration of response (DOR) based on RECIST 1.1; Arms D, E, F: DOR based on iRECIST; Arms D, E, F: Progression-free survival (PFS) based on RECIST 1.1; Arms D, E, F: PFS based on iRECIST; Arms A, B, F: Number of participants with positive anti-drug antibodies (ADAs) against GSK6097608; Arms A, B, F: Titers of ADAs against GSK6097608; Arms B, D, E, F: Number of participants with positive ADAs against dostarlimab; Arms B, D, E, F: Titers of ADAs against dostarlimab; Arms E, F: Number of participants with positive ADAs against GSK4428859A (EOS884448); Arms E, F: Titers of ADAs against GSK4428859A (EOS884448); Arms A, B, F: Maximum observed concentration (Cmax) for GSK6097608; Arms A, B, F: Minimum observed concentration (Cmin) for |
### Table: Clinical Trials on Dostarlimab

| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
| GSK6097608; Arms A, B, F: | Area under the plasma concentration-time curve from time zero extrapolated to infinity (AUC[0-infinity]) for GSK6097608; Arms A, B, F: | | | | | | |
| GSK6097608; Arms A, B, F: | Area under the plasma concentration-time curve from time zero to time (AUC[0-t]) for GSK6097608; Arms A, B, F: | | | | | | |
| GSK6097608; Arms B, D, E, F: | Cmax for dostarlimab; Arms B, D, E, F: | | | | | | |
| GSK6097608; Arms B, D, E, F: | Cmin for dostarlimab; Arms B, D, E, F: AUC(0-infinity) for dostarlimab; Arms B, D, E, F: AUC(0-t) for dostarlimab; Arms B, D, E, F: t1/2 for dostarlimab; Arms E, F: | | | | | | |
| GSK4428859A (EOS884448); Arms E, F: | Cmin for GSK4428859A (EOS884448); Arms E, F: AUC(0-infinity) for GSK4428859A (EOS884448); Arms E, F: AUC(0-t) for GSK4428859A (EOS884448); Arms E, F: t1/2 for GSK4428859A (EOS884448) | | | | | | |

**Citation:** Jahangir MA, Kumar N, Shahab MS. Dostarlimab “A Miracle Drug Against Cancer”: Current Knowledge and On-going Clinical Trials. Int J Biomed Investig 2021; 5: 140. doi: [10.31531/2581-4745.1000140](10.31531/2581-4745.1000140)
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
| NCT03602859 | A Phase 3 Comparison of Platinum-based Therapy With TSR-042 and Niraparib Versus Standard of Care (SOC) Platinum-based Therapy as First-line Treatment of Stage III or IV Nonmucinous Epithelial Ovarian Cancer | Ovarian Neoplasms; Ovarian Cancer | Drug: Niraparib; Drug: Dostarlimab (TSR-042); Drug: Placebo; Drug: Standard of care; Drug: Dostarlimab/Placebo; Drug: Niraparib/Placebo | PFS for PD-L1 positive participants; PFS for all participants; Blinded Independent Central Review (BICR) for PD-L1 positive participants; BICR for all the participants; PFS per investigator-assessed immune-related PD-L1 positive participants; PFS per investigator-assessed immune-related for all the participants; Overall Survival (OS) of PD-L1 positive participants; OS of all the participants; Number of PD-L1 positive participants with treatment-emergent adverse events (TEAEs); Number of overall participants with TEAEs; Number of PD-L1 positive participants with serious adverse events (SAEs); Number of overall participants with SAEs; Number of PD-L1 positive participants with treatment discontinuations or dose delays or dose reductions due to adverse events; Number of all the participants with treatment discontinuations or dose delays or dose reductions due to adverse events; Number | Tesaro, Inc.; European Network of Gynaecological Oncological Trial Groups (ENGOT) | Phase 3 | 45 |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
|            |       |            |               | of PD-L1 positive participants with immune-related adverse events of interest (irAEIs); Number of all the participants with irAEIs; Number of PD-L1 positive participants with changes in Eastern Cooperative Oncology Group (ECOG) performance status; Number of overall participants with changes in ECOG performance status; Number of PD-L1 positive participants with abnormal hematology results; Number of all the participants with abnormal hematology results; Number of PD-L1 positive participants with abnormal blood chemistry results; Number of all the participants with abnormal blood chemistry results; Change from Baseline in the European Quality of Life 5-Dimension 5-Level Scale (EQ-5D-5L) assessment among PD-L1 positive participants; Change from Baseline in the EQ-5D-5L assessment among all participants; Change from Baseline in the European Organization for Research and |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|-----------------------|--------|------------|
|            |       |            | Treatment of Cancer Quality of Life Questionnaire C30 (EORTC-QLQ-C30) assessment among PD-L1 positive participants; Change from Baseline in the EORTC-QLQ-C30 assessment among all the participants; Change from Baseline in the EORTC-QLQ Ovarian Cancer Module OV28 (EORTC-QLQ-OV28) assessment among PD-L1 positive participants; Change from Baseline in the EORTC-QLQ-OV28 assessment among all the participants; Time to symptom worsening in the EQ-5D-5L assessment among the PD-L1 positive participants; Time to symptom worsening in the EQ-5D-5L assessment among all the participants; Time to symptom worsening in the EORTC QLQ-C30 assessment among the PD-L1 positive participants; Time to symptom worsening in the EORTC QLQ-C30 assessment among all the participants; Time to symptom worsening in the EORTC QLQ-OV28 assessment among the PD-L1 positive participants; Time to symptom worsening in the EORTC QLQ-OV28 assessment among all the participants; |
### Table

| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            |       |            | positive participants; Time to symptom worsening in the EORTC-QLQ-OV28 assessment among all the participants; Time to first subsequent therapy (TFST) in PD-L1 positive participants; TFST in all the participants; Time to second subsequent therapy (TSST) in PD-L1 positive participants; TSST in all the participants; Time to progression on next-line therapy (PFS2) in PD-L1 positive participants; PFS2 in all the participants; Objective Response Rate (ORR) among PD-L1 positive participants; ORR among all the participants; Pathologic complete response (pCR) rate among PD-L1 positive participants; pCR rate among all the participants; Duration of response (DOR) in PD-L1 positive participants; DOR in all the participants; Disease control rate (DCR) in PD-L1 positive participants; DCR in all the participants; Maintenance progression-free survival (MPFS) in PD-L1 |
| NCT Number   | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                                | Phases   | References |
|--------------|----------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------|----------|------------|
| NCT04165772 | Study of Induction PD-1 Blockade in Subjects With Locally Advanced Mismatch Repair Deficient Solid Tumors | Rectal Adenocarcinoma; Clinical Stage: Stage II (T3-4, N-); Stage III (Any T, N+); Solid Tumor; Solid Tumor, Adult | Drug: TSR-042 or Dostarlimab; Drug: capecitabine or 5-FU; Radiation: Intensity Modulated Radiation Therapy (IMRT) | Pathologic complete response (pCR) or complete clinical response (cCR) at 12 months | Memorial Sloan Kettering Cancer Center; Tesaro, Inc. | Phase 2  | 46         |
| NCT05277051 | First-Time-in-Human Study of GSK4381562 in Participants With Advanced Solid Tumors | Neoplasms                                                                  | Drug: GSK4381562; Drug: Dostarlimab                                           | Number of participants with dose-limiting toxicities (DLTs); Number of participants with adverse events (AEs) and serious adverse events (SAEs); Number of participants with AEs and SAEs by severity; Duration of AEs and SAEs; Number of participants with clinically significant changes in laboratory parameters, electrocardiogram (ECG) and vital signs; Number of participants with dose reductions or delays; Number of participants with withdrawals due to AEs; Overall response rate (ORR); Number of participants with positive antidrug antibodies (ADA) to GSK4381562; Titers of ADA to GSK4381562; | GlaxoSmithKline                        | Phase 1  | 47         |
| NCT Number  | Title                                                                 | Conditions        | Interventions                                      | Outcome Measures                                                                                           | Sponsor/Collaborators | Phases | References |
|------------|----------------------------------------------------------------------|-------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------|--------|------------|
| NCT03308942 | Effects of Single Agent Niraparib and Niraparib Plus Programmed Cell Death-1 (PD-1) | Neoplasms         | Drug: Niraparib; Biological: Pembrolizumab; Biological: TSR-042 (Dostarlimab) | Number of participants with positive ADA to dostarlimab; Titers of ADA to dostarlimab; Plasma concentrations of GSK4381562; Maximum observed plasma concentration (Cmax) of GSK4381562 monotherapy; Cmax of GSK4381562 in combination with dostarlimab; Minimum observed plasma concentration (Cmin) of GSK4381562 monotherapy; Cmin of GSK4381562 in combination with dostarlimab; Area under the plasma concentration curve from time zero to last time of quantifiable concentration (AUC[0-t]) of GSK4381562; AUC(0-t) of GSK4381562 in combination with dostarlimab; AUC from time zero to infinity (AUC[0-infinity]) of single dosing of GSK4381562; AUC(0-infinity) of single dosing of GSK4381562 in combination with dostarlimab | Tesaro, Inc.          | Phase 2 | 48         |
| NCT Number | Title                                      | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                                                                                                                                                 | Sponsor/Collaborators | Phases | References |
|------------|--------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------|------------|
|            | Inhibitors in Non-Small Cell Lung Cancer   | Participants                                                              |                                                                                | Stage 2: Cohort 1A and Cohort 2A: Objective Response Rate; Stage 1: Cohort 1: Number of Participants With Non-serious Adverse Events (Non-SAEs) and Serious Adverse Events (SAEs); Stage 1: Cohort 2: Number of Participants With Non-SAEs and SAEs; Stage 1: Cohort 3: Number of Participants With Non-SAEs and SAEs; Stage 2: Cohorts 1A and 2A: Number of Participants With Non-SAEs and SAEs; Stage 1: Cohort 1: Number of Participants Discontinuing the Study Due to AEs; Stage 1: Cohort 2: Number of Participants Discontinuing the Study Due to AEs; Stage 1: Cohort 3: Number of Participants Discontinuing the Study Due to AEs; Stage 2: Cohorts 1A and 2A: Number of Participants Discontinuing the Study Due to AEs; Stage 1: Cohort 1: Duration of Response; Stage 1: Cohort 2: Duration of Response; Stage 1: Cohort 3: Duration of Response; Stage 2: Cohorts 1A and 2A: Duration of Response |                      |        |            |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            |               | of Response; Stage 1: Cohort 1: Disease Control Rate; Stage 1: Cohort 2: Disease Control Rate; Stage 1: Cohort 3: Disease Control Rate; Stage 2: Cohorts 1A and 2A: Disease Control Rate; Stage 1: Cohort 1: Progression-free Survival; Stage 1: Cohort 2: Progression-free Survival; Stage 1: Cohort 3: Progression-free Survival; Stage 2: Cohorts 1A and 2A: Progression-free Survival; Stage 1: Cohort 1: Plasma Concentration of Niraparib Following Combination Therapy of Niraparib and Pembrolizumab; Stage 1: Cohort 2: Plasma Concentration of Niraparib Following Combination Therapy of Niraparib and Pembrolizumab; Stage 1: Cohort 3: Plasma Concentration of Niraparib Following Niraparib Monotherapy; Stage 2: Cohorts 1A and 2A: Plasma Concentration of Niraparib Following Combination |
| NCT Number   | Title                                                                 | Conditions     | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators          | Phases | References |
|--------------|-----------------------------------------------------------------------|----------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------|--------|------------|
| NCT03250832 | Study of TSR-033 With an Anti-programmed Cell Death-1 Receptor (PD-1) in Participants With Advanced Solid Tumors | Neoplasms      | Drug: TSR-033; Drug: Dostarlimab; Drug: mFOLFOX6; Drug: FOLFIRI; Drug: Bevacizumab | Part 1a, Part 1c and 2B: Number of participants experiencing DLT; Part 1: Number of participants with serious adverse events (SAEs), treatment-emergent AEs (TEAEs) and immune-related AEs (irAEs); Part 2B: Number of participants with SAEs, TEAEs and irAEs; Part 1: Number of participants with abnormality in hematology parameters; Part 2B: Number of participants with abnormality in clinical chemistry parameters; Part 1: Number of participants with abnormality in clinical chemistry parameters; Part 2B: Number of participants with abnormality in electrocardiogram (ECG) parameters; Part 2B: Number of participants with abnormality in ECG parameters; Part 2A: Objective response rate (ORR); Part 1a: | Tesaro, Inc.; GlaxoSmithKline | Phase 1 | 49         |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            |       |            |               | Area under the concentration-time curve from time zero to last measurable concentration (AUC [0-last]) of TSR-033; Part 1b: AUC (0-last) of TSR-033; Part 1c: AUC (0-last) of TSR-033 and dostarlimab; Part 1a: AUC extrapolated from time zero to infinity (AUC[0-inf]) of TSR-033; Part 1b: AUC (0-inf) of TSR-033; Part 1c: AUC (0-inf) of TSR-033 and dostarlimab; Part 1a: AUC over a dosing interval at steady state (AUCtau) of TSR-033; Part 1b: AUCtau of TSR-033; Part 1c: AUCtau of TSR-033 and dostarlimab; Part 1a: Maximum concentration (Cmax) of TSR-033; Part 1b: Cmax of TSR-033; Part 1c: Cmax of TSR-033 and dostarlimab; Part 1a: Clearance (CL) of TSR-033; Part 1b: CL of TSR-033; Part 1c: CL of TSR-033 and dostarlimab; Part 1a: Volume of distribution at steady state (Vss) of TSR-033; Part 1b: Vss of TSR-033; Part 1c: Vss of TSR-033 and dostarlimab; Part 1a: Terminal half-life (t1/2) of TSR-033; | | | |
| NCT Number   | Title                                                                 | Conditions | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                  | Phases | References |
|-------------|-----------------------------------------------------------------------|------------|------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------|--------|------------|
| NCT02723955| Dose Escalation and Expansion Study of GSK3359609 in Participants With Selected Advanced Solid Tumors (INDUCE-1) | Neoplasms  | Drug: feladilimab (GSK3359609); Drug: GSK3174998; Drug: Pembrolizumab; Drug: Docetaxel; Drug: Pemetrexed; Drug: Paclitaxel plus Carboplatin; Drug: Gemcitabine plus Carboplatin; Drug: Fluorouracil (5-FU) plus carboplatin or cisplatin; Drug: Dostarlimab; Drug: Cobolimab; Drug: Bintrafusp alfa | Part 1b: t1/2 of TSR-033; Part 1c: t1/2 of TSR-033 and dostarlimab; Part 1: Number of participants with anti-TSR-033 antibodies; Part 2: Number of participants with anti-TSR-033 antibodies; Part 1: ORR; Part 2: Duration of response (DOR); Part 2: Disease control rate (DCR) | GlaxoSmithKline; Merck Sharp & Dohme LLC | Phase 1 | 50         |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
|            |       |            |               | response rate (ORR); Parts 1 and 2: Maximum observed plasma concentration (Cmax) and minimum observed plasma concentration (Cmin) of GSK3359609; Parts 1 and 2: Area under the concentration-time curve over the dosing interval (AUC[0-tau]) of GSK3359609 in plasma; Parts 1 and 2: Number of participants with positive results in Anti-drug antibody (ADA) test by GSK3359609 dose level; Part 1 and 2: Number of participants with positive results in GSK3359609; Part 2: Number of participants with DLT following administration of GSK3359609 in combination with chemotherapies; Part 2: Cmax and Cmin of GSK3174998; Part 2: AUC(0-tau) of GSK3174998; Part 2: Cmax and Cmin of Pembrolizumab; Part 2: AUC(0-tau) of Pembrolizumab; Part 2: Number of participants with positive results in ADA test by GSK3359609 in combination |            |            |            |
| NCT Number    | Title                                      | Conditions                        | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                  | Phases | References |
|--------------|--------------------------------------------|-----------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------|--------|------------|
| NCT03651206 | Recurrent Ovarian Carcinoma Sarcoma Anti-pd-1 Niraparib | Ovarian Carcinoma; Carcinosarcoma; Endometrial Carcinosarcoma | Drug: Niraparib; Combination Product: Niraparib + TSR-042 (Dostarlimab); Drug: Chemotherapy Drugs | with pembrolizumab or GSK3174998 dose level; Part 2: Number of participants with positive results in Pembrolizumab; Part 2: Number of participants with positive results in GSK3174998; Part 2: Cmax and Cmin of GSK3359609 combination with chemotherapies; Part 2: Number of participants with positive results in ADA test by GSK3359609 combination with chemotherapies dose level; Part 2: Cmax and Cmin of dostarlimab; Part 2: AUC(0-tau) of dostarlimab; Part 2: Cmax and Cmin of cobolimab; Part 2: AUC(0-tau) of cobolimab; Part 2: Cmax and Cmin of bintrafusp alfa; Part 2: AUC(0-tau) of bintrafusp alfa | ARCAGY/GINECO GROUP; Tesaro, Inc. | Phase 2 | Phase 3    | 51         |
### Referenced Studies

**Citation:** Jahangir MA, Kumar N, Shahab MS. Dostarlimab “A Miracle Drug Against Cancer”: Current Knowledge and On-going Clinical Trials. Int J Biomed Investig 2021; 5: 140. doi: 10.31531/2581-4745.1000140

| NCT Number | Title                                                                                                           | Conditions                                                                                     | Interventions                                               | Outcome Measures                                                                 | Sponsor/ Collaborators                      | Phases | References |
|------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------|---------|------------|
| NCT05065021 | Using Genetic Profile to Determine the Treatment for Patients With Ovarian Cancer Who Previously Received a PARP-inhibitor | Ovarian Cancer; Fallopian Tube Cancer; Primary Peritoneal Cancer; High Grade Serous Cancer; High Grade Endometrioid Cancer | Drug: Niraparib; Drug: Dostarlimab; Drug: Bevacizumab; Drug: Paclitaxel | Percentage of participants that achieve biomarker-guided treatment; Response rate percentage; Overall response rate for Cohort A; Overall response rate for Cohort B; Overall response rate for initial cohort/Cohort C; Progression-free survival rate for initial cohort/Cohort C; Progression-free survival rate for initial cohort/Cohort A; Progression-free survival rate for initial cohort/Cohort B; CA125 response rate for initial cohort/Cohort C; CA125 response rate for Cohort A; CA125 response rate for Cohort B; Disease control rate for initial cohort/Cohort C; Disease control rate for Cohort A; Disease control rate for Cohort B; Percentage of participants with adverse events in the initial cohort/Cohort C; Percentage of participants with adverse events in Cohort A; Percentage of participants with adverse events in Cohort B | University Health Network, Toronto; GlaxoSmithKline | Phase 2 | 52         |
| NCT Number | Title                                                                 | Conditions               | Interventions                                      | Outcome Measures                                                                 |
|------------|----------------------------------------------------------------------|--------------------------|----------------------------------------------------|----------------------------------------------------------------------------------|
| NCT03016338| Study of Niraparib and TSR-042 in Recurrent Endometrial Cancer       | Endometrial Cancer       | Drug: Niraparib; Drug: TSR-042                     | Clinical benefit rate; Number of side effects; Overall response rate; Duration of response; Progression free survival rate; Overall survival rate |
| NCT04126200| Platform Study of Belantamab Mafodotin as Monotherapy and in Combination With Anti-cancer Treatments in Participants With Relapsed/Refractory Multiple Myeloma (RRMM) (DREAMM 5) | Multiple Myeloma         | Drug: Belantamab mafodotin; Drug: GSK3174998; Drug: Feladilimab; Drug: Nirogacestat; Drug: Dostarlimab; Drug: Isatuximab; Drug: Lenalidomide; Drug: Dexamethasone; Drug: Pomalidomide | DE Phase: Number of participants achieving dose limiting toxicities (DLT); DE Phase: Number of participants with adverse events (AEs) and serious adverse events (SAEs); DE Phase: Number of participants with clinically significant changes in hematology, clinical chemistry and urinalysis lab parameters; CE Phase: Number of participants achieving Overall Response Rate (ORR); DE Phase: Number of participants achieving ORR; CE Phase: Number of participants achieving Clinical Benefit Rate (CBR); DE Phase: Number of participants achieving Partial Response (PR); CE Phase: Number of participants achieving PR; DE Phase: Number of participants achieving Very Good Partial Response (VGPR); CE Phase: |

**Citation:** Jahangir MA, Kumar N, Shahab MS. Dostarlimab “A Miracle Drug Against Cancer”: Current Knowledge and On-going Clinical Trials. Int J Biomed Investig 2021; 5: 140. doi: 10.31531/2581-4745.1000140
| NCT Number | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                                                                                                                                                 | Sponsor/Collaborators | Phases | References |
|------------|----------------------------------------------------------------------|-----------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------|------------|
|            | Number of participants achieving VGPR; DE Phase: Number of participants achieving Complete Response (CR); CE Phase: Number of participants achieving CR; DE Phase: Number of participants achieving stringent Complete Response (sCR); CE Phase: Number of participants achieving sCR; DE Phase: Belantamab mafodotin concentrations when administered in combination with anti-cancer treatments; CE Phase: Belantamab mafodotin concentrations when administered in combination with anti-cancer treatments; DE Phase: GSK3174998 concentration when administered in combination with belantamab mafodotin; CE Phase: GSK3174998 concentration when administered in combination with belantamab mafodotin; DE Phase: Feladilimab concentration when administered in combination with belantamab mafodotin; CE Phase: Feladilimab |                                                                 |                                                                                           |                                                                                                                                     |                       |        |            |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            |               | concentration when administered in combination with belantamab mafodotin; DE Phase: Nirogacestat concentration when administered in combination with belantamab mafodotin; CE Phase: Nirogacestat concentration when administered in combination with belantamab mafodotin; DE Phase: Dostarlimab concentration when administered in combination with belantamab mafodotin; CE Phase: Dostarlimab concentration when administered in combination with belantamab mafodotin; DE Phase: Isatuximab concentration when administered in combination with belantamab mafodotin; CE Phase: Isatuximab concentration when administered in combination with belantamab mafodotin; DE Phase: Concentration of anti-drug antibodies (ADAs) against belantamab mafodotin when administered in combination with anti-cancer | | | |
NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References
--- | --- | --- | --- | --- | --- | --- | ---
| | | | | treatments; CE Phase: Concentration of ADAs against belantamab mafodotin when administered in combination with anti-cancer treatments; DE Phase: Concentration of ADAs against GSK3174998 when administered in combination with belantamab mafodotin; CE Phase: Concentration of ADAs against GSK3174998 when administered in combination with belantamab mafodotin; DE Phase: Concentration of ADAs against feladilimab when administered in combination with belantamab mafodotin; CE Phase: Concentration of ADAs against feladilimab when administered in combination with belantamab mafodotin; DE Phase: Concentration of ADAs against dostarlimab when administered in combination with belantamab mafodotin; DE Phase: Concentration of ADAs against dostarlimab when administered in combination with belantamab mafodotin; | | |
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| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|-------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
|             |       |            | Concentration of ADAs against isatuximab when administered in combination with belantamab mafodotin; CE Phase: Concentration of ADAs against isatuximab when administered in combination with belantamab mafodotin; DE Phase: Number of participants with adverse events of special interest (AESI) for belantamab mafodotin; CE Phase: Number of participants with AESI for belantamab mafodotin; DE Phase: Number of participants with AESI for GSK3174998; CE Phase: Number of participants with AESI for GSK3174998; DE Phase: Number of participants with AESI for Feladilimab; CE Phase: Number of participants with AESI for Feladilimab; DE Phase: Number of participants with AESI for Nirogacestat; CE Phase: Number of participants with AESI for Nirogacestat; DE Phase: Number of participants with AESI for Dostarlimab; CE Phase: Number of participants with AESI for Dostarlimab; DE Phase: Number of participants with AESI for Dostarlimab; |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|-------------|
|            |       |            | with AESI for Dostarlimab; DE Phase: Number of participants with AESI for Isatuximab; CE Phase: Number of participants with AESI for Isatuximab; DE Phase: Number of participants with abnormal ocular findings on ophthalmic examination; CE Phase: Number of participants with abnormal ocular findings on ophthalmic examination; CE Phase: Number of participants achieving Progression-free survival (PFS); CE Phase: Duration of response (DoR); CE Phase: Time to response (TTR); CE Phase: Number of participants achieving Overall survival (OS); CE Phase: Number of participants with AEs and SAEs; CE Phase: Number of participants with AEs leading to discontinuation; CE Phase: Number of participants with dose reduction or delay; CE Phase: Number of participants with clinically significant changes in hematology, clinical chemistry and urinalysis lab parameters |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/ Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|------------------------|--------|------------|
| NCT03739710 | Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) | Neoplasms | Drug: Docetaxel; Drug: Feladlimab; Drug: Ipilimumab; Drug: GSK4428859A/EOS884448; Drug: Dostarlimab; Drug: GSK6097608 | Part 1: Number of participants with any adverse events (AEs) and serious adverse events (SAEs); Part 1: Number of participants with dose limiting toxicity (DLT); Part 1: Number of participants with clinically significant changes in vital signs, physical examination and laboratory parameters; Part 1: Number of participants requiring dose modifications; Part 2: Overall survival; Part 1: Objective response rate; Part 1: Disease control rate (DCR); Part 1: Maximum observed concentration (Cmax) and Minimum observed concentration (Cmin) of feladlimab; Part 1: Cmax and Cmin of ipilimumab; Part 1: Cmax and Cmin of GSK4428859A/EOS884448; Part 1: Cmax and Cmin of dostarlimab; Part 1: Cmax and Cmin of GSK6097608; Part 2: Survival rate at 12 and 18 months; Part 2: Number of participants with CR, Partial response (PR), Stable disease (SD) and Progressive disease (PD); Part 2: Progression-free survival | GlaxoSmithKline; iTeos Belgium SA | Phase 2 | 55 |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            |       |            |               | survival (PFS); Part 2: Objective response rate (ORR); Part 2: Duration of response (DOR); Part 2: DCR; Part 2: Number of participants with immune-based (i) iCR, iPR, unconfirmed progressive disease (iUPD), confirmed progressive disease (iCPD), and iSD; Part 2: Progression-free survival (iPFS); Part 2: Objective response rate (iORR); Part 2: Duration of response (iDOR); Part 2: Number of participants with AEs, adverse events of special interest (AESI), SAEs and AE/SAEs leading to dose modifications/delays/withdrawals; Part 2: Number of participants with clinically significant changes in vital signs, physical examination and laboratory parameters; Part 2: Cmax and Cmin for SoC (docetaxel); Part 2: Cmax and Cmin for feladilimab; Part 2: Number of participants with positive anti-drug antibodies (ADA) against docetaxel; Part 2: Number of participants with |
| NCT Number  | Title                                                                 | Conditions                                                                 | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                      | Phases       | References |
|------------|----------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------|-------------|-------------|
| NCT05060432| Study of EOS-448 With Standard of Care and/or Investigational Therapies in Participants With Advanced Solid Tumors | Advanced Cancer; Lung Cancer; Head and Neck Cancer; Melanoma                | Drug: EOS-448; Drug: pembrolizumab; Drug: inupadenant; Drug: Dostarlimab; Drug: SOC chemotherapies | Positive ADA against feladilimab                                                         | iTeos Belgium SA; GlaxoSmithKline; iTeos Therapeutics | Phase 1; Phase 2 | 56          |
| NCT01042379| I-SPY TRIAL: Neoadjuvant and Personalized Adaptive Novel Agents to Treat Breast Cancer | Breast Neoplasms; Breast Cancer; Breast Tumors; Angiosarcoma; TNBC - Triple-Negative Breast Cancer; HER2-positive Breast Cancer; HER2-negative Breast Cancer; Hormone Receptor Positive | Drug: Standard Therapy; Drug: AMG 386 with or without Trastuzumab; Drug: AMG 479 (Ganitumab) plus Metformin; Drug: MK-2206 with or without Trastuzumab; Drug: AMG 386 and Trastuzumab; Drug: T-DM1 and Pertuzumab; Drug: Pertuzumab and | Determine whether adding experimental agents to standard neoadjuvant medications increases the probability of pathologic complete response (pCR) over standard neoadjuvant chemotherapy for each biomarker signature established at trial entry.; Establishing predictive and prognostic indices based on QuantumLeap Healthcare Collaborative | QuantumLeap Healthcare Collaborative          | Phase 2      | 57          |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       | Tumor; Hormone Receptor Negative Tumor; Early-stage Breast Cancer; Locally Advanced Breast Cancer | Trastuzumab; Drug: Ganetespib; Drug: ABT-888; Drug: Neratinib; Drug: PLX3397; Drug: Pembrolizumab - 4 cycle; Drug: Talazoparib plus Irinotecan; Drug: Patritumab and Trastuzumab; Drug: Pembrolizumab - 8 cycle; Drug: SGN-LIV1A; Drug: Durvalumab plus Olaparib; Drug: SD-101 + Pembrolizumab; Drug: Tucatinib plus trastuzumab and pertuzumab; Drug: Cemiplimab; Drug: Cemiplimab plus REGN3767; Drug: Trilaciclib with or without trastuzumab + pertuzumab; Drug: SYD985 ([vic-trastuzumab duocarmazine]; Drug: Oral Paclitaxel + Encequidar + Dostarlimab (TSR-042) + Carboplatin with or without trastuzumab; Drug: Oral Paclitaxel + Encequidar + | qualification and exploratory markers to predict pCR and residual cancer burden (RCB).; To determine three- and five-year relapse-free survival (RFS) and OS among the treatment arms.; To determine incidence of adverse events (AEs), serious adverse events (SAEs), and laboratory abnormalities of each investigational agent tested.; MRI Volume |
| NCT Number | Title                                                                 | Conditions       | Interventions                                                                 | Outcome Measures                                                                 | Sponsor/Collaborators                                                                 | Phases | References |
|------------|-----------------------------------------------------------------------|------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------|------------|
| NCT03654833 | Mesothelioma Stratified Therapy (MiST) : A Multi-drug Phase II Trial in Malignant Mesothelioma | Mesothelioma, Malignant | Drug: Rucaparib; Drug: Abemaciclib; Drug: pembrolizumab & bevacizumab; Drug: Atezolizumab & Bevacizumab; Drug: Dostarlimab and Niraparib | Disease control rate (DCR) at 12 weeks assessed by modified RECIST 1.1, in patients with relapsed mesothelioma.; Disease control rate (DCR) at 24 weeks assessed by modified RECIST 1.1, in patients with relapsed mesothelioma.; Objective response rate (ORR) assessed for 12 months; Safety assessed according to CTCAE criteria.; Toxicity assessed according to CTCAE criteria. | University of Leicester; British Lung Foundation; Clovis Oncology, Inc.; Eli Lilly and Company; Merck Sharp & Dohme LLC; BerGenBio ASA; Roche Pharma AG; University Hospitals, Leicester; The Christie NHS Foundation Trust; GlaxoSmithKline | Phase 2 | 58         |
| NCT04673448 | Niraparib and TSR-042 for the Treatment of BRCA-Mutated Unresectable or Metastatic Breast, Pancreas, Ovary, Fallopian Tube, or Anatomic Stage III Breast Cancer AJCC v8; Anatomic Stage IIA Breast Cancer AJCC v8; Anatomic Stage IIB Breast Cancer AJCC v8; | Anatomic Stage III Breast Cancer AJCC v8; Anatomic Stage IIA Breast Cancer AJCC v8; Anatomic Stage IIB Breast Cancer AJCC v8; | Biological: Dostarlimab; Drug: Niraparib | Best objective response; Incidence of adverse events; Progression-free survival (PFS); Duration of response (DOR); Disease control (DC); Overall survival | University of Washington; GlaxoSmithKline | Phase 1 | 59         |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
| Primary Peritoneal Cancer | Anatomic Stage IIIC Breast Cancer AJCC v8; Anatomic Stage IV Breast Cancer AJCC v8; BRCA-Mutated Malignant Neoplasm; BRCA-Mutated Metastatic Breast Carcinoma; BRCA-Mutated Ovarian Carcinoma; Metastatic Breast Carcinoma; Metastatic Fallopian Tube Carcinoma; Metastatic Malignant Solid Neoplasm; Metastatic Ovarian Carcinoma; Metastatic Pancreatic Carcinoma; Metastatic Primary Peritoneal Carcinoma; Prognostic Stage III Breast Cancer AJCC v8; | | | | | | |

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| NCT Number | Title | Conditions                                                                 | Interventions                                                                 | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|----------------------------------------------------------------------------|-------------------------------------------------------------------------------|------------------|-----------------------|--------|------------|
|            |       | Prognostic Stage IIIA Breast Cancer AJCC v8; Prognostic Stage IIIB Breast   |                                                                                |                  |                       |        |            |
|            |       | Cancer AJCC v8; Prognostic Stage IIIC Breast Cancer AJCC v8; Prognostic     | Stage III Fallopian Tube Cancer AJCC v8; Stage III Ovarian Cancer AJCC v8;    |                  |                       |        |            |
|            |       | Stage IV Breast Cancer AJCC v8; Stage III Fallopian Tube Cancer AJCC v8;   | Stage III Ovarian Cancer AJCC v8; Stage III Pancreatic Cancer AJCC v8; Stage  |                  |                       |        |            |
|            |       | Stage III Peritoneal Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer AJCC  | Stage IIIA Ovarian Cancer AJCC v8; Stage IIIA Primary Peritoneal Cancer AJCC   |                  |                       |        |            |
|            |       | v8; Stage IIIA Fallopian Tube Cancer AJCC v8; Stage IIIA Ovarian Cancer     | v8; Stage IIIA Primary Peritoneal Cancer AJCC v8; Stage IIIA Fallopian Tube    |                  |                       |        |            |
|            |       | AJCC v8; Stage IIIA Ovarian Cancer AJCC v8; Stage IIIA Primary Peritoneal   | Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer AJCC v8; Stage IIIA Fallopian |                  |                       |        |            |
|            |       | Cancer AJCC v8; Stage IIIA Primary Peritoneal Cancer AJCC v8; Stage IIIA    | Tube Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer AJCC v8; Stage IIIA     |                  |                       |        |            |
|            |       | Fallopian Tube Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer AJCC v8;   | Fallopian Tube Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer AJCC v8;      |                  |                       |        |            |
|            |       | Stage IIIA Fallopian Tube Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer  | Stage IIIA Fallopian Tube Cancer AJCC v8; Stage IIIA Fallopian Tube Cancer     |                  |                       |        |            |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
|            | Ovarian Cancer AJCC v8; Stage IIIA2 Fallopian Tube Cancer AJCC v8; Stage IIIA2 Ovarian Cancer AJCC v8; Stage IIIB Fallopian Tube Cancer AJCC v8; Stage IIIB Ovarian Cancer AJCC v8; Stage IIIB Primary Peritoneal Cancer AJCC v8; Stage IIC Fallopian Tube Cancer AJCC v8; Stage IIC Ovarian Cancer AJCC v8; Stage IIC Primary Peritoneal Cancer AJCC v8; Stage IV Fallopian Tube Cancer AJCC v8; Stage IV Ovarian Cancer AJCC v8; Stage IV Ovarian Cancer AJCC v8; Stage IV Pancreatic Cancer AJCC v8; Stage IV Primary Peritoneal Cancer AJCC v8; | | | | | | |
| NCT Number | Title | Conditions                                                                 | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|-----------------------------------------------------------------------------|---------------|------------------|-----------------------|--------|------------|
|            |       | Stage IVA Fallopian Tube Cancer AJCC v8; Stage IVA Ovarian Cancer AJCC v8;   |               |                  |                       |        |            |
|            |       | Stage IVA Primary Peritoneal Cancer AJCC v8; Stage IVB Fallopian Tube Cancer |               |                  |                       |        |            |
|            |       | AJCC v8; Stage IVB Ovarian Cancer AJCC v8; Stage IVB Primary Peritoneal      |               |                  |                       |        |            |
|            |       | Cancer AJCC v8; Unresectable Breast Carcinoma; Unresectable Fallopian Tube  |               |                  |                       |        |            |
|            |       | Carcinoma; Unresectable Malignant Solid Neoplasm; Unresectable Ovarian      |               |                  |                       |        |            |
|            |       | Carcinoma; Unresectable Pancreatic Carcinoma; Unresectable                  |               |                  |                       |        |            |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|---------|------------|
| NCT02715284 | Study of TSR-042, an Anti-programmed Cell Death-1 Receptor (PD-1) Monoclonal Antibody, in Participants With Advanced Solid Tumors | Neoplasms | Biological: Dostarlimab | Part 1: Number of participants with treatment emergent AEs (TEAEs); Part 1: Number of participants with immune related AEs of interest; Part 1: Number of participants with abnormal hematology parameters; Part 1: Number of participants with abnormal clinical chemistry parameters; Part 1: Number of participants with abnormal thyroid function; Part 1: Number of participants with abnormal urine parameters; Part 1: Number of participants with abnormal vital signs; Part 1: Number of participants with abnormal electrocardiogram (ECG) parameters; Part 1: Number of participants with abnormal physical examination.; Part 1: Number of participants receiving concomitant medications; Part 2A: Number of participants with TEAEs; Part 2A: Number of participants with immune related AEs of interest; Part 2A: Number of participants | Tesaro, Inc. | Phase 1 | 60 |
## Table 1: Clinical Trials of Dostarlimab

| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            |               | with abnormal hematology parameters; Part 2A: Number of participants with abnormal clinical chemistry parameters; Part 2A: Number of participants with abnormal thyroid function; Part 2A: Number of participants with abnormal urine parameters; Part 2A: Number of participants with abnormal vital signs; Part 2A: Number of participants with abnormal ECG; Part 2A: Number of participants with abnormal physical examination; Part 2A: Number of participants receiving concomitant medications; Part 2B: Number of participants with TEAEs; Part 2B: Number of participants with immune related AEs of interest; Part 2B: Number of participants with abnormal hematology parameters; Part 2B: Number of participants with abnormal clinical chemistry parameters; Part 2B: Number of participants with abnormal thyroid function; Part 2B: Number of participants with abnormal thyroid function |            |                      |  | |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|-----------------------|--------|------------|
|            |       |            |               | abnormal urine parameters; Part 2B: Number of participants with abnormal vital signs; Part 2B: Number of participants with abnormal ECG parameters; Part 2B: Number of participants with abnormal physical examination; Part 2B: Number of participants receiving concomitant medications; Part 2B: Cohort A1 Overall Response Rate (ORR) by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1; Part 2B: Cohort F ORR by RECIST version 1.1; Part 2B: Cohort A2 ORR by RECIST version 1.1; Part 2B: Cohort G ORR by RECIST version 1.1; Part 2B: Cohort E ORR by immune related Response Evaluation Criteria in Solid Tumors per irRECIST; Part 2B: Cohort A1 Duration of response (DOR); Part 2B: Cohort F Duration of response (DOR); Part 2B: Cohort A2 Duration of response (DOR); Part 2B: Cohort A1 ORR by independent blinded central review using RECIST version |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            |               | 1.1; Part 2B: Cohort F ORR by independent blinded central review using RECIST version 1.1; Part 2B: Cohort A1 Immune-related objective response rate (irORR) by irRECIST; Part 2B: Cohort A2 irORR by irRECIST; Part 2B: Cohort F irORR by irRECIST; Part 2B: Cohort G irORR by irRECIST; Part 2B: Cohort A1 Duration of response (DOR) based on independent blinded central review using RECIST version 1.1; Part 2B: Cohort F DOR based on independent blinded central review using RECIST version 1.1; Part 2B: Cohort G DOR based on independent blinded central review using RECIST version 1.1; Part 2B: Cohort A1 Disease control rate; Part 2B: Cohort A2 Disease control rate; Part 2B: Cohort F Disease control rate; Part 2B: Cohort G Disease control rate; Part 2B: Immune related disease control rate; Part 2B: Immune related duration of response; Part 2B: Progression free survival; Part 2B: Overall survival; Part 1: |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|------------------|----------------------|--------|------------|
|            | Area under the concentration-time curve from time 0 to last (AUC,0-last) assessment of dostarlimab; Part 1: Area under the concentration-time curve from time 0 to infinity (AUC, 0-infinity) of dostarlimab; Part 1: Minimum concentration (Cmin) of dostarlimab; Part 1: Maximum concentration (Cmax) of dostarlimab; Part 1: Clearance (CL) of dostarlimab; Part 1: Volume of distribution (Vz) of dostarlimab; Part 1: Area under the concentration-time curve at steady state (AUC,ss) of dostarlimab; Part 1: Minimum concentration at steady state (Cmin,ss) of dostarlimab; Part 1: Maximum concentration at steady state (Cmax,ss) of dostarlimab; Part 2A : AUC,0-last assessment of dostarlimab; Part 2A: AUC, 0-infinity of dostarlimab; Part 2A: Cmin of dostarlimab; Part 2A: Cmax of dostarlimab; Part 2A: CL of dostarlimab; Part 2A: Vz of dostarlimab; Part 2A: AUC,ss of dostarlimab; Part 2A: Cmin,ss of dostarlimab; Part 2A: Cmax,ss of dostarlimab; |
| NCT Number | Title | Conditions | Interventions | Outcome Measures | Sponsor/Collaborators | Phases | References |
|------------|-------|------------|---------------|-----------------|----------------------|--------|------------|
|            |       |            | of dostarlimab; Part 2B: AUC,0-last assessment of dostarlimab; Part 2B: AUC, 0-infinity of dostarlimab; Part 2B: Cmin of dostarlimab; Part 2B: Cmax of dostarlimab; Part 2B: CL of dostarlimab; Part 2B: Vz of dostarlimab; Part 2B: AUC,ss of dostarlimab; Part 2B: Cmin,ss of dostarlimab; Part 2B: Cmax,ss of dostarlimab |