Nivolumab in Treating Patients With Autoimmune Disorders and Advanced, Metastatic, or Unresectable Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

* Patients can have either histologically confirmed malignancy that is radiologically evaluable and metastatic or unresectable, or have a malignancy for which a PD-1/PD-L1 inhibitor has been approved in the adjuvant setting. Eligible tumor types include solid tumors and malignancies in which there is known evidence of clinical activity for single agent PD-1 or PD-L1 antibodies. Nivolumab is Food and Drug Administration (FDA)-approved for the treatment of melanoma, non-small cell lung cancer (NSCLC), Merkel cell cancer, bladder cancer, renal cell carcinoma (RCC), gastric cancer, hepatocellular carcinoma (HCC), cervical cancer, head and neck cancer, Hodgkin lymphoma (HL), metastatic small cell lung cancer (SCLC), and any solid tumor with microsatellite instability (MSI)-high status confirmed. Patients with HL are eligible but must follow standard response criteria. Additional tumor types may be eligible on a case by case basis upon discussion with principal investigator (PI). Patients enrolling on the trial for adjuvant use will be restricted to those with histology for which a PD-1/PD-L1 inhibitor has been approved in the adjuvant setting including but not limited to NSCLC, melanoma, RCC, cervical cancer, and bladder cancer * Patients who have previously received other forms of immunotherapy (high-dose \[HD\] IL-2, IFN, CTLA-4) are allowed. Patients must not have received cytokine immunotherapy for at least 4 weeks before nivolumab administration. Patients who have received prior anti-CTLA4 will be allowed and the washout period is 6 weeks * Age \>= 18 years; children are excluded from this study but may be eligible for future pediatric phase 1 combination trials * Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 (Karnofsky \>= 60) * Life expectancy of greater than 12 weeks * Leukocytes \>= 1,000/mcL * Absolute neutrophil count \>= 500/mcL * Platelets \>= 50,000/mcL * Total bilirubin =\< 2 x institutional upper limit of normal (ULN) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 5 x institutional ULN or =\< 8 x institutional ULN for patients with liver metastases or an autoimmune disease that is contributing to the elevation of these values * Creatinine ULN OR glomerular filtration rate (GFR) \>= 30 mL/min (if using the Cockcroft-Gault formula) * Human immunodeficiency virus (HIV)-infected patients on effective antiretroviral therapy with undetectable viral load within 6 months are eligible for this trial * If evidence of chronic hepatitis B virus (HBV) infection, HBV viral load must be undetectable on suppressive therapy if indicated * If history of hepatitis C virus (HCV) infection, must be treated with undetectable HCV viral load * Patients with new or progressive brain metastases (active brain metastases) or leptomeningeal disease are eligible if the treating physician determines that immediate central nervous system (CNS) specific treatment is not required and is unlikely to be required for at least 4 weeks (or scheduled assessment after the first cycle of treatment), and a risk-benefit analysis (discussion) by the patient and the investigator favors participation in the clinical trial * The effects of nivolumab on the developing human fetus are unknown. For this reason, women of child-bearing potential (WOCBP) and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. WOCBP receiving nivolumab will be instructed to adhere to contraception for a period of 5 months after the last dose of investigational product. Men receiving nivolumab and who are sexually active with WOCBP will be instructed to adhere to contraception for a period of 7 months after the last dose of investigational product. Women of childbearing potential must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotropin \[HCG\]) within 24 hours prior to the start of nivolumab. Women must not be breastfeeding. Women who are not of childbearing potential (i.e., who are postmenopausal or surgically sterile as well as azoospermic men) do not require contraception. WOCBP is defined as any female who has experienced menarche and who has not undergone surgical sterilization (hysterectomy or bilateral oophorectomy) or who is not postmenopausal. Menopause is defined clinically as 12 months of amenorrhea in a woman over 45 in the absence of other biological or physiological causes. In addition, women under the age of 55 must have a documented serum follicle stimulating hormone (FSH) level less than 40 mIU/mL. These durations have been calculated using the upper limit of the half-life for nivolumab (25 days) and are based on the protocol requirement that WOCBP use contraception for 5 half-lives plus 30 days, and men who are sexually active with WOCBP use contraception for 5 half-lives plus 90 days. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she (or the participating partner) should inform the treating physician immediately * Ability to understand and the willingness to sign a written informed consent document * Patients with more than one autoimmune disease are eligible. The treating physician would determine which autoimmune disease is dominant and the patient would be treated under that specific cohort

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Exclusion Criteria:

* Patients who have had chemotherapy or radiotherapy within 2 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study or those who have not recovered from adverse events (AEs) due to agents administered more than 4 weeks earlier have not resolved or stabilized. Palliative (limited-field) radiation therapy (RT) is permitted (2 week washout from start of treatment), if all of the following criteria are met: * Repeat imaging demonstrates no new sites of bone metastases * The lesion being considered for palliative radiation is not a target lesion * Patients with prior therapy with an anti-PD-1 or anti-PD-L1 * Patients with prior allogeneic hematologic transplant * Patients who are receiving any other anticancer investigational agents * Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, BIOLOGICAL: Nivolumab

Conditions:
Autoimmune Disease, Crohn Disease, Dermatomyositis, Hematopoietic and Lymphoid Cell Neoplasm, Inflammatory Bowel Disease, Malignant Solid Neoplasm, Multiple Sclerosis, Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Sjogren Syndrome, Systemic Lupus Erythematosus, Systemic Scleroderma, Ulcerative Colitis

More Information

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