Safety and Tolerability Study of GIM-122 in Subjects With Advanced Solid Malignancies

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

General * Written informed consent * ECOG performance status 0-1. * Laboratory assessment 28 days prior to enrollment for assessment of acceptable cardiac, renal and hepatic functions * Recommended Double methods of contraception 90-days post treatment Cancer Specific * Histologically or cytologically confirmed locally advanced/unresectable or metastatic solid tumor * Received FDA approved treatment of PD-1 inhibitor or PD-L1 inhibitor for advance malignant tumors and have progressed/relapsed, are refractory, or intolerant * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1 * Had prior therapy with PD-1/PD-L1 inhibitors. Other checkpoint inhibitors (ie, CTLA4, LAG3) are permitted if they did not lead to treatment discontinuation * No other lines of therapy that are available

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Exclusion Criteria:

General * Enrolled in any other interventional clinical trial, starting within 4 weeks of the first dose of GIM-122 and throughout the duration of the study, or is receiving other therapy directed at their malignancy * Women who are pregnant or breastfeeding * History of cardiac issues, pulmonary embolism, active and clinically significant bacterial, fungal, or viral infection ≤ 6 months prior to dosing * Contraindications to the imaging assessments or other study procedures that subjects will undergo or any medical or social condition that, in the opinion of the investigator, might place a subject at an increased risk, affect compliance, or confound safety or other clinical study data interpretation Cancer Specific * Current second malignancy at other sites * Leptomeningeal disease * Spinal cord compression * Symptomatic or new or enlarging central nervous system (CNS) metastases Treatment-specific Exclusion Criteria * Ongoing toxicity \> Grade 1 from prior therapy according to Common Terminology Criteria for Adverse Events (CTCAE) v 5.0 * Has undergone a major surgery \< 1 month prior to administration of GIM-122 * Has received radiation therapy within 2 weeks prior to administration of GIM-122 * Has undergone or is anticipated to undergo organ transplantation including allogeneic or autologous stem cell transplantation at any time * Has received systemic anti-cancer therapy within 2 weeks and cytotoxic agents that have a major delayed toxicity within 4 weeks, of the first dose of GIM-122 * Prior treatment with other immune modulating agents within \< 4 weeks prior to the first dose of GIM-122. * Has a diagnosis of immunodeficiency, either primary or acquired * Has received treatment with systemic steroids or any form of immunosuppressive therapy within 14 days prior to administration of GIM-122 * Has active or prior history of autoimmune disease, including ulcerative colitis and Crohn's disease, or any condition that requires systemic steroids. * Has a known severe intolerance to or hypersensitivity reactions to monoclonal antibodies, Fc-bearing proteins, or IV immunoglobulin preparations; prior history of human anti-human antibody response; known allergy to any of the study medications, or excipients in the various formulations of any agent. * Has received live vaccines within 30 days of study initiation (inactivated vaccines are allowed; seasonal vaccines should be up to date \> 30 days prior to administration of GIM-122).

Conditions & Interventions

Interventions:
DRUG: GIM122
Conditions:
Advanced Solid Malignancies
Keywords:
solid tumor, advanced malignancies, GIM-122

More Information

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