Background: MICA/MICB are Pan-Cancer Targets

MICA expression is highly restricted on normal tissues, and is only expressed on the cell surface in response to cellular stress, such as infection, radiation, or malignant transformation.

Levels of MICA and MICB are in solid tumors during normal protein synthesis with survivors, whereas high expression on cancer cells shows a beneficial impact on survival.

Background: CLN-619 Proposed Modes of Action

CLN-619 is efficacious in vivo in mice with tumors

CLN-619-001 Study Schema

This is an open-label, first-in-human, multicenter, dose escalation and dose expansion study of CLN-619 administered alone (Module A) or in combination with pembrolizumab (Module B) in patients with advanced solid tumors.

Key Eligibility Criteria

• Age >= 18 years
• ECOG 0 or 1
• Estimated life expectancy >=12 weeks
• Histologically or cytologically confirmed metastatic or locally advanced, unresectable solid tumors
• Patients should have received any other available standard therapy (except cohort B1)
• Estimated life expectancy >=12 weeks
• ECOG 0 or 1
• Histologically or cytologically confirmed metastatic or locally advanced, unresectable solid tumors
• Patients should have received any other available standard therapy (except cohort B1)
• History of grade 1 or lower radiation toxicity to the target organ or organ system.
• Inclusion criteria: Patients who are deemed to be intolerant to cancer therapy or whose control may be jeopardized by the complications of the therapy

Exclusion Criteria

• Invasive malignancy (cancer with metastasis or distant spread).
• Patients with a history of severe or life-threatening adverse reactions to previous treatments.
• Patients with a history of significant medical conditions that require systemic corticosteroids or other immunosuppressive medications.
• Patients with active infections or ongoing use of systemic antimicrobial agents.
• Patients with a history of severe allergic reactions to previous treatments.
• Patients with a history of severe or life-threatening adverse reactions to previous treatments.

Study Information

• Principal Investigator: Dr. Hamilton E. Mehta
• Status: Monotherapy (Module A) and combination therapy (Module B) dose escalation is ongoing

References: