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Anti-mesothelin vaccine CRS-207 with or without low-dose cyclophosphamide plus chemotherapy as front-line treatment for malignant pleural mesothelioma (MPM)

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Background

CRS-207 is live-attenuated, double-deleted *Listeria monocytogenes* (LADD) engineered to express the tumor-associated antigen mesothelin which is highly expressed in malignant pleural mesothelioma (MPM). CRS-207 stimulates potent innate and adaptive immunity and in combination with chemotherapy may act synergistically to alter the tumor environment to be more susceptible to immune-mediated killing. Preliminary data of 32 patients who received CRS-207 in combination with pemetrexed/cisplatin showed 60% partial responses and 94% disease control[1]. Low-dose cyclophosphamide (Cy) in combination with LADD improved immune and anti-tumor responses and overall survival in preclinical studies.

Methods

Up to 60 subjects are planned to be enrolled in 2 mutually exclusive, sequential cohorts at 5 clinical trial sites. Patients must be chemotherapy-naïve, have unresectable MPM, good performance status (ECOG 0 or 1) and adequate organ function. Eligible patients in Cohort 1 receive 2 prime vaccinations with CRS-207 (1×10^9 CFU; 250 mL IV over 2 hours) 2 weeks apart, followed by up to 6 cycles of pemetrexed (500 mg/m^2) and cisplatin (75 mg/m^2) 3 weeks apart and 2 CRS-207 boost vaccinations 3 weeks apart. Subjects are followed every 8 weeks until disease progression. Clinically stable patients continue CRS-207 maintenance vaccinations every 8 weeks. Patients in Cohort 2 receive low-dose Cy (200 mg/m^2) 1 day prior to each CRS-207 vaccination. Objectives of the study are safety, immunogenicity, objective tumor responses and tumor marker kinetics.

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