BACKGROUND AND OBJECTIVES

SV-BR-1 is a breast cancer cell line with features of antigen-presenting cells including HLA class II expression (Lacher, Front Immunol. 2018 May 7). Patients who match SV-BR-1 at 1 or more HLA alleles may be likely to respond to treatment based on previous observations.

"Monotherapy" Study (YRD-MGB-007): The SV-BR-1 GM regimen includes: low dose cyclophosphamide to reduce immune suppression (300 mg/m² 2-3 days prior to inoculation); 20-40 million irradiated SV-BR-1 GM cells intradermally; and interferon-β2b (10,000 IU x 4) into the inoculation sites – all given within 24 hours of inoculation. In mice, SV-BR-1 GM inoculation, a skin test for immediate hypersensitivity is conducted using irradiated SV-BR-1 parent cells or to SV-BR-1 GM (1x10⁷ cells/ml) in the vehicle.

Combination Therapy Study (BR-RLO-001): Methylcellulose (200 mg IV) in combination with the regimen from the Monotherapy study with cycles every 3 weeks.

The objectives are to evaluate the immunological and functional activity of the SV-BR-1 GM regimen with or without pembrolizumab (KEYTRUDA).