SHINE; A Phase 2/3, Single-Arm Study with 2 Cohorts to Characterize and Evaluate the Efficacy, Safety, and Tolerability of hu14.18K322A Treatment Given Alone and in Combination with Chemotherapy in Participants with High-Risk Neuroblastoma Refractory to Treatment; Renaissance EPG-HU1418-201

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- ages 18 months to younger than 18 years - diagnosed with histologically proven high-risk neuroblastoma that has spread to other parts of the body - have disease that can be evaluated or measured - have recovered from the effects of prior cancer treatment - see the ClinicalTrials.gov link for complete inclusion criteria

Exclusion Criteria:

- have an active uncontrolled infection - have another cancer besides neuroblastoma - have had a recent stem cell transplant or a solid organ transplant - are pregnant or breastfeeding - see the ClinicalTrials.gov link for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: hu1418K322A + Temozolomide + Irinotecan
Conditions:
Cancer, Children's Health, Rare Diseases
Keywords:
Brain, Brain Cancer, Cancer, Childhood Cancer, Metastatic Neuroblastoma

More Information

Description: This study is testing the use of drug along with chemotherapy in children and young people with high-risk neuroblastoma that has spread to other parts of the body. We want to learn how safe the treatment is and how well it may work. What we learn from this study may help improve future treatment options for children and young people with high-risk neuroblastoma.
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Phase: PHASE2
IRB Number: STUDY00026723