Clinical Study for Children and Adults 13 to 30 Years Old With Refractory Non-CNS Solid Tumors

What:

This is a phase I dose escalation study of intratumoral herpes simplex virus-1 mutant HSV1716 in subjects with refractory non-central nervous system solid tumors.

Investigational Product:

- HSV1716, an oncolytic virus that replicates in and lyses the dividing cells of tumors but fails to replicate in normal post-mitotic cells
- Administered via intratumoral injection

Objectives:

- Determine safety of intratumoral injection of HSV1716
- Measure antiviral immune response
- Measure systemic viremia following intratumoral HSV1716
- Measure antitumor activity (within the confines of a Phase I study)

Main Inclusion Criteria:

- Progressive or refractory non-CNS solid tumor for which no curative therapy is known
- At least one lesion >18mm in each of 3 dimensions or tumor volume >3mL per volumetric measurements
- Subjects with metastasis to the brain are eligible but no CNS sites will be injected
- Age ≥13 and ≤ 30 years at time of consent

Main Exclusion Criteria:

- > 4 weeks after use of an unlicensed or investigational product
- Prior allogeneic hematopoietic stem cell transplant
- GVHD subsequent to autologous stem cell transplant
- Leukemia

Study Location:

Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue, Cincinnati, OH 45229
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Principal Investigator:

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