UF HEALTH CANCER CENTER
RE-MATCH CLINICAL TRIAL
UF IRB 128-2013

A research study for pediatric patients with
Recurrent Medulloblastoma and
Recurrent Cerebral Primitive
Neuroectodermal Tumors (PNETs)

Fast Facts Brochure

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RE-MATCH Fast Facts

RE-MATCH is a Phase II clinical trial evaluating the safety of autologous tumor-specific T-cell immunotherapy in conjunction with total tumor RNA-loaded dendritic cell, or DC, vaccination in patients with recurrent medulloblastoma and recurrent cerebral primitive neuroectodermal tumors, or PNETs.

This study includes four distinct parts:
- Surgery
- Induction
- Consolidation
- Adoptive cellular immunotherapy

Up to 42 patients will be enrolled in the single-arm Phase II trial. All subjects will undergo surgical resection of recurrent tumor for disease debulking and preparation of tumor RNA.

Subjects with localized recurrence and who are suitable for high-dose chemotherapy and peripheral blood stem cell transplant (HDC+PBSCT) will be enrolled in Group A.

Subjects with disseminated disease or who are otherwise unsuitable for HDC+PBSCT will be enrolled in Group B and receive salvage chemotherapy.

Subjects will undergo leukapheresis prior to and during induction/salvage chemotherapy to collect sufficient cells for DC generation, autologous T-cell expansion and peripheral blood stem cell rescue.

All subjects will receive either induction chemotherapy (Group A patients receiving Cyclophosphamide, Etoposide and Temozolomide) or salvage therapy (Group B patients receiving Etoposide and Temozolomide) followed by consolidation therapy with either myeloablative chemotherapy (Group A patients receiving Carboplatin, Etoposide and Thiopeta followed by autologous PBSC rescue) or non-myeloablative chemotherapy (Group B patients receiving Cyclophosphamide and Fludarabine).

Subsequently, all subjects will receive adoptive transfer of tumor-specific T cells with concurrent intradermal tumor RNA-loaded DC vaccination. DC vaccines will be given at two-week intervals for a total of three vaccines. Subjects will be followed until tumor progression and/or death due to any cause.

Subject inclusion criteria
- Age: 0 to ≤ 30 years old
- Histopathologic diagnosis of recurrent or progressive medulloblastoma or cerebral PNET
- Able to undergo surgical debulking of recurrent disease
- Failed standard radiotherapy (craniospinal + focal boost)
- Suitable candidate for high-dose chemotherapy with autologous PBSC rescue or salvage chemotherapy

Subject exclusion criteria
- Receiving chronic immunosuppressive medication(s)
- Known immunosuppressive disease