Immunocine Cancer Center

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Participant Inclusion Criteria

In order to be eligible to participate in this treatment plan, an individual must meet all of the following criteria:

i. Provision of signed and dated informed consent form.

ii. Stated willingness to comply with all procedures and availability for the duration of the treatment.

iii. Male or female, aged 18 years and older.

iv. Diagnosed with a solid cancer deemed to be of poor prognosis, refractory, late stage, and/or with limited treatment options. Patients with typically good standard of care options need to have either already failed this therapy, be declining that therapy for reasons unrelated to Immunocine, or executing that therapy in addition to IDCT.

- B Cell cancers may be considered if there is a sizeable mass capable of being biopsied, pathologically confirmed to be at least 50% malignant, and the rest of treatment is considered feasible and safe (case-by-case determination).

v. A cancerous lesion must be at least 2cm in any 1 diameter, and able to be biopsied. *Not required if previous tumor sample was collected and cryopreserved elsewhere and can be transported to Immunocine.*

vi. Multiple lesions may be added together to reach the 2cm minimum.

vii. A biopsy must be predicted to be at least 50% tumorous material.

viii. Ability to adhere to the bi-weekly injections of IDCT vaccine regimen.

ix. For females of reproductive potential: use of highly effective contraception for at least 1 month prior to screening and agreement to use such a method during study participation and for an additional 12 weeks following discontinuations of last vaccination. Must have a negative serum pregnancy test prior to first treatment.

x. For males of reproductive potential: use of condoms or other methods to ensure effective contraception with partner during study participation and for an additional 12 weeks following discontinuations of last vaccination.

xi. Adequate kidney, liver, bone marrow function, and immune function, as follows:

- Hemoglobin ≥ 8.0 gm/dL
- Absolute neutrophil count (ANC) ≥ 1,500 cells/mm3
- Platelet count ≥ 75,000 /mm3
- Total bilirubin ≤ 1.5 times upper limit of normal (ULN),
- Aspartate transaminase AST (SGOT) and alanine aminotransferase ALT (SGPT) ≤2.5 times the ULN
- Albumin >2g/dL
- White blood count ≥ 3,000/uL and ≤ 11,000/uL
- Acceptable clotting abilities
- PT: 10-16 seconds
- PTT: 26-45 seconds

xii. Able to comply with the requirement to be off strong immunosuppressive drugs for at least 21 days before IDCT and during the IDCT process.

- Note that this is a requirement before IDCT treatment and not medical review.
- This does not necessarily include all chemotherapy and/or radiation as not all are detrimentally immunosuppressive.

xiii. ECOG performance status ≤ 2.

xiv. No concomitant lymphohematopoietic pathologies that would interfere with Dendritic Cell procurement, maturation, loading or T cell activity.

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Participant Exclusion Criteria

An individual who meets any of the following criteria will be excluded from IDCT treatment:

i. Tumors deemed unable to be biopsied.

- Potentially overcome if previous cancer tissue has been stored to preserve mRNA.

ii. No tumorous lesion either separate or in aggregate with other lesions would reach 2cm.

iii. The presence of tumorous lesions within the brain.

- Note that this does not necessarily include lesions within the skull, and the risk of 50% pseudoprogression will need to be evaluated by the medical team.
- Certain brain cancers can be treated if resected and cryopreserved at home, a post-op scan reveals minimal residual disease in the brain cavity, and the rest of treatment is considered feasible and safe (case-by-case determination).

iv. The presence of tumorous lesions within the heart.

v. If cancer is estimated to occupy more than 30% of the airway space.

vi. If the estimation of an enlargement of any lesion would cause an emergent medical situation (e.g. the spine is of considerable note).

- If lesion ≤ 7cm in 1 direction; estimate UL of 50% increase.
- If lesion ≥ 7.5cm in 1 direction; estimate UL of 25% increase.
- Note that this does not preclude the potential of pain or side effects, but focuses on emergent, potentially catastrophic outcomes.
- Risk can often be preventively mitigated with localized radiation.

vii. Female patients who are pregnant breast feeding or of childbearing potential without a negative pregnancy test prior to baseline. Post- menopausal women must be amenorrheic for at least 12 months to be considered of non-childbearing potential.

viii. Non-B Cell hematological malignancies, or B Cell cancers that do not fall within inclusion considerations.

ix. Bone disease must be carefully analyzed, especially if involvement of the spine is suspected. Patients with bone disease are excluded if they meet at least 3 of any of the following: ECOG of 2 or worse, Calcium level is already above 10.2mg/dL, there is already evidence of kidney failure, the patient's threshold for pain is considered low, they are immobile, there is a high risk of fracture if any bone lesion expands by just 25%, there is high risk of spinal nerve compression if any bone lesion expands by just 25%.

i. Cancers of the eyes

ii. Cancers of the testicles

iii. Autoimmune disorders are not necessarily a disqualifier but can be. Some guidelines are below:

Autoimmune Disorder	IDCT Treatable	Conditions	Likely to include a Rheumatologist During IDCT
Type 1 Diabetes	Yes		
Vitiligo	Yes		
Celiac Disease	Yes		
Psoriasis	Yes	If not severe, active, or recently active	Yes
Sjogren's Syndrome	Yes		Yes
Rheumatoid Arthritis	Yes	Will be case-by-case based on severity and medications	Yes
Hashimoto's Disease	Yes	If thyroid is absent	Yes
Chron's Disease	Yes	If bowel is absent	Yes
Lupus	Yes	Dendritic Cells only, Case-by-case	Yes
Multiple Sclerosis	No		
Graves Disease	No		
Myasthenia Gravis	No		