



Morphogenesis expands the use of its intralesional cancer vaccine into patients with advanced Merkel cell carcinoma or cutaneous squamous cell carcinoma

Tampa, Florida, January 29, 2020 -- The FDA has allowed Morphogenesis to expand its human clinical trials using its ImmuneFx (IFx) cancer vaccine technology into two more types of cancer, advanced Merkel cell carcinoma (MCC) and cutaneous squamous cell carcinoma (cSCC).

Cancer vaccines like IFx-Hu2.0 initiate and focus the enormous power of the immune system on the destruction of tumor cells. Morphogenesis' cancer vaccine technology, called IFx does this in the most effective manner possible. By expressing a bacterial antigen on the surface of a patient's own tumor cells, IFx-Hu2.0 primes and educates the immune system to destroy tumor cells throughout the body without harming healthy cells and tissues. The IFx-Hu2.0 vaccine is also currently being tested in a Phase I clinical trial for Stage III/IV unresectable cutaneous melanomas.

About the Study:

Approximately twenty adult patients, of any sex, ethnicity, and race with histologically confirmed MCC or cSCC with accessible lesions, will be eligible for study enrollment and treatment with IFx-Hu2.0 (i.e. 20 total patients across both indications).

Patients must have at least one injectable lesion, defined as an easily palpable superficial lesion that can be accurately localized, stabilized by palpation, and is superficial enough to enable intralesional injection. To be eligible for this study, patients must have progressed despite standard therapy(ies), or are intolerant to or refused standard therapy(ies).

Enrollees will receive IFx-Hu2.0 as monotherapy at up to three time points. This is primarily a safety study that is designed to evaluate IFx-Hu2.0 as a monotherapy and provide foundational evidence to potentially support further studies investigating IFx-Hu2.0 + anti-PD-1 combination therapy for patients with advanced MCC or cSCC.

For individuals interested in participating in the clinical trial, please select the following link for further information:

[ClinicalTrials.gov \(Study NCT number 04160065\)](https://clinicaltrials.gov/ct2/show/study/NCT04160065)

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About Morphogenesis, Inc.

Morphogenesis is a clinical-stage company based in Tampa, Florida developing novel cell and gene therapies. It is developing “off-the-shelf” personalized immunotherapies for the treatment of cancer. The Company’s patented immunotherapy is based on a single bacterial gene that when expressed on the surface of a patient’s tumor cells, educates the immune system to target the patient’s unique set of tumor antigens (neoantigens) without toxic effects. Year on year, Morphogenesis continues to reach major milestones towards its goal of bringing their gene therapy to human cancer patients. Last year, Morphogenesis augmented its portfolio with three US patent awards and made multiple applications for worldwide patent protection. These patents are an important component of Morphogenesis’ exclusive intellectual property portfolio that includes some 30 issued patents and patent applications.

For more information visit Morphogenesis-Inc.com

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