Neuromedin U (u-Neuropeptide Y; /Neurotensin (NT)) associates with gastrin-releasing protein (GRP) which stimulates cell proliferation, and satiety, reducing cholecystokinin (CCK) and gastrin. CCK expression is upregulated in response to stress, suggesting an interlinking of psychological stress and gut health. This may affect the gut microbiome, which is known to influence the expression of the gut-brain axis. The gut microbiome also plays a role in the development of psychiatric disorders such as anxiety and depression, and it is known that individuals with these disorders have a different gut microbiome composition compared to healthy controls.

Methods

Methods: A phase 1 study of Oncolytic Immunotherapeutic Metastatic Endothelial Genes (OMEN) is a phase 1 clinical trial that aims to evaluate the safety, tolerability, and efficacy of a novel oncolytic virus therapy in patients with advanced solid tumors. The primary objective of the study is to determine the maximum tolerated dose (MTD) and the recommended phase 2 dose (RP2D) of the oncolytic virus therapy. The secondary objectives include assessing the safety, tolerability, and immunogenicity of the therapy.

Results: Clinical and Biometric Outcomes

- Safety: The study is evaluating the safety profile of the oncolytic virus therapy. The safety data will be assessed by monitoring adverse events, laboratory tests, and vital signs.
- Efficacy: The study is assessing the efficacy of the oncolytic virus therapy by evaluating the objective response rate (ORR), progression-free survival (PFS), and overall survival (OS).

Results: CT Assessment

- CT scans will be performed at baseline and at key time points during the study to evaluate the changes in the tumor size, shape, and density.

Results: Assessment of Change in STRT

- STRT measures will be calculated using the Response Evaluation Criteria in Solid Tumors (RECIST) criteria.

Results: PET/CT Assessment

- PET/CT scans will be performed at baseline and at key time points during the study to evaluate the changes in the tumor metabolism.

Results: Analysis of Immunological Outcomes

- Immunological outcomes will be assessed by evaluating the changes in the immune cell infiltration and expression of immunogenic genes.

Conclusions

- This is the first clinical trial of an oncolytic virus therapy in patients with advanced solid tumors.
- The study aims to determine the MTD and RP2D of the oncolytic virus therapy.
- The study will provide insights into the safety, tolerability, and efficacy of the therapy.
- The results of this study will inform the design of future clinical trials of oncolytic virus therapy.

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