PI: Jose Trevino, MD and Esha Madan, PhD
Title: To Observe Efficiency of Flower Monoclonal Antibody Therapy in Pancreatic Cancer

Pancreatic ductal adenocarcinomas (PDAC) cancer presents numerous challenges for effective treatment and the five-year survival remains bleak, at about 9% overall. Efforts to develop more effective treatments are vital to change the current trajectory of this disease's impact on patients. Targeting the tumor microenvironment (TME) is a burgeoning field in cancer therapy. Stopping the growth of metastatic niches of PDAC in other organs remains one of the most critical challenges in improving survival rates for this aggressive disease. We have discovered an archaic anticancer neighborhood watchdog protection system which functions locally in organs. Cancer intelligently defeats this system. We found that every cell in the human body has its own fitness called “Cell Fitness. Based on this fitness, cells make a decision regarding their behavior with the neighbors. Unfit neighboring cells often suffer abuse and are killed. The evolutionary character of cancer and distilled it to a simple concept of “war” between the bully and the victim. Cancer is an aggressor, a cellular bully which victimizes the host cells in the affected organ. A comprehensive understanding of the archaic anti-cancer system has led our laboratory to develop a humanized Anti-Flower Monoclonal antibody (Aenya). Aenya targets the Flower Code in cancer and its microenvironment cells. This monoclonal Ab therapy empowers the host cells within the TME to mount a formidable defense against cancer cells. Functioning like a protective cage, our therapy not only restricts cancer cells but also enhances the efficacy of standard chemotherapy, when used in conjugation. Our first aim is to test the anti-cancer potential of Flower monoclonal Abs in the pancreatic cancer PDX model. In a 8-week study Flower mAB doses 20mg/kg, 40mg/kg and 60 mg/kg (based on preliminary data) once every week for 4 weeks will be administered alone or in combination with 5- FU, Oxaliplatin, Irinotecan, Gemcitabine and Abraxane. Tumor volumes, tumor metastasis and mice survival will be recorded. Our second aim is to perform a toxicology analysis of the 20/40 and 60 mg/kg dose for Flower monoclonal Ab in mice model. We will collect the blood, serum samples and important organs (brain, lung, liver, heart, colon, kidney, pancreas, spleen, muscle tissue and lymph nodes). We will analyze any tissue toxicity in the important organs with the help of H&E, tunnel and caspase-3 staining. We will study the blood inflammation markers (ESR, CRP, IL-6), kidney toxicity markers (serum creatinine, creatinine/protein ratio), liver toxicity markers (ALT and AST), cardiotoxicity marker (troponin-1), muscle cachexia marker (GDF15), blood micro-clotting signature (D-Dimer). Importantly, the preventive nature of our therapy alleviates the physical, emotional, and economic burdens associated with cancer diagnosis and treatment, culminating in a substantial improvement in public health by alleviating the cancer burden within the communities. We request support towards further development of Anti-Flower Monoclonal antibody (Aenya) towards IND enabling and Phase I clinical trial to help treat PDAC.